IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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VACCINES FOR CHILDREN

PROGRAM MANUAL

FOR ILLINOIS VFC PROVIDERS

PROTECTING HEALTH, IMPROVING LIVES

CONTENTS

MODULE 1: OVERVIEW OF THE VFC PROGRAM

VACCINES FOR CHILDREN (VFC)

The Vaccines for Children (VFC) program is a federally-funded program from the Centers for Disease Control and Prevention (CDC) that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay. The benefits of the VFC program include:

- Reducing referrals of children from private providers to state health departments for vaccination.
- Saving VFC-enrolled providers out-of-pocket expenses for vaccine.
- Eliminating or reducing vaccine cost as a barrier to immunizing eligible children.

VFC providers contribute to increased immunization coverage level rates and reduced delays in immunizations and, subsequently, the risk of serious illness or death from vaccine-preventable diseases.

The Illinois Department of Public Health (the Department) administers the VFC program to provide immunizations for children under the age of 19 who are uninsured ("self-pay"), Medicaid-eligible, American Indian or Alaskan Native. Underinsured children (children who have limited coverage or caps on the amount of vaccines allowed annually) can access VFC vaccines recommended by the CDC's Advisory Committee on Immunization Practices (ACIP) at participating federally qualified health centers (FQHC) and rural health clinics (RHC), or local health departments (LHD) under an approved deputization agreement. All VFC providers must offer all ACIP-recommended vaccines for the populations they serve.

This program manual is intended for providers currently enrolled in the Illinois VFC program. Providers located within the City of Chicago should contact the Chicago Department of Public Health via phone (312-746-6050) or e-mail (ChicagoVFC@cityofchicago.org).

Note: In Illinois, the state does not require parental or guardian consent for vaccination. Local administrators of clinics and/or health departments may require consent under local agency guidance. However, CDC and the Department view required consent as a possible barrier to vaccination. Provision of a vaccine information statement (VIS) must be routinely provided prior to vaccinating.

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that was established in 1964 to provide advice and guidance on the most effective means to prevent vaccine-preventable diseases. In 1993, Congress gave the ACIP unique legal authority to determine recommendations for the routine administration of vaccines to children and adults in the civilian population. The ACIP is the only entity in the federal government that makes such recommendations. These recommendations include:

- Age for vaccine administration
- Number of doses and dosing interval
- Precautions and contraindications

Major functions of the ACIP are as follows:

- Develops technical recommendations on vaccine use and immunization practices.
- Approves vaccines to be provided through the VFC program.

- Recommends immunization schedules that are harmonized with recommendations of other advisory groups, such as the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).

VFC AND I-CARE IN ILLINOIS

The Illinois Immunization Section requires VFC providers to be enrolled and active users of the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE). Additional information and forms for I-CARE are available at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/icare. The Immunization Section has integrated its VFC enrollment and vaccine management functions into I-CARE. This integration allows for greater accountability and programmatic oversight.

All Illinois VFC providers must provide individual patient immunization records on how each VFC vaccine was administered. The individual patient immunization records can either be manually entered directly into I-CARE or can be electronically transmitted to I-CARE from the provider's electronic medical record (EMR) system. VFC providers not in compliance will not be able to continue participating in the VFC program.

FEE CAPS ON VACCINE ADMINISTRATION

Illinois VFC providers may charge a vaccine administration fee for non-Medicaid VFC-eligible children only. Providers are not allowed to bill non-Medicaid VFC eligible children for the cost of the VFC vaccine. As of January 1, 2013, the vaccine administration fee may not exceed the administration fee cap of $23.87 per vaccine dose. The administration fee must be waived if the parent cannot afford to pay it.

MODULE 2: ELIGIBILITY

VFC ELIGIBILITY CRITERIA

Providers must screen for and document VFC eligibility with every visit. Provider forms are in the appendix, as well in I-CARE under "Immunization Links."

To be eligible to receive VFC vaccine, children (regardless of their state of residency) must be younger than 19 and meet at least one of the following criteria:

- **Medicaid-eligible**: a child who is eligible for the Medicaid program. (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance covered by Medicaid, including All Kids.)
- **Uninsured**: a child who has no health insurance coverage. (May also be referred to as "Self-Pay".)
- **American Indian or Alaskan Native (AI/AN)**: as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).
- **Underinsured**: a child who has health insurance, but the coverage does not include vaccines or a child whose insurance covers only selected vaccines. Children who are underinsured for select vaccines are VFC-eligible for non-covered vaccines only.

UNDERINSURED CHILDREN

Underinsured children are eligible to receive all ACIP recommended VFC vaccines ONLY through a federally qualified health center (FQHC), rural health clinic (RHC), or local health department (LHD) under an approved deputization agreement.

The following are common scenarios occurring among underinsured children and would qualify patients for access to VFC vaccine at a FQHC, RHC or a deputized LHD:

- Underinsured children include those children who have commercial (private) health insurance (e.g. Blue Cross/Blue Shield or Aetna), but the coverage does not include vaccinations, making the child VFC-eligible for non-covered vaccines only. This child is then considered underinsured for the purposes of the VFC program and can acquire access to recommended VFC vaccines only at a FQHC, RHC or a deputized LHD.

- Underinsured children whose coverage does not allow all ACIP recommended vaccines (e.g. HPV vaccine or influenza vaccine). Once the vaccines covered by the commercial insurance are administered, these children are considered underinsured. The child must be referred to a FQHC, RHC or a deputized LHD to access VFC vaccine for the ACIP recommended vaccines not covered by their commercial insurance.

- Underinsured children whose coverage caps the number of allowable provider visits (e.g. only five visits covered annually). Once the child has exceeded the number of provider visits allowed and the insurance will not cover the cost of additional vaccines needed in the annual period, the child is then considered underinsured for the purposes of the VFC program and can access VFC vaccine at a FQHC, RHC or a deputized LHD.

- Underinsured children whose insurance caps vaccine coverage at a certain dollar amount (e.g. Visits not to exceed $1,500 annually). Once that coverage amount is reached, these children meet the criteria of being underinsured. To be eligible to access VFC vaccine once that insurance dollar amount has been met, these children must be referred to a FQHC, RHC or a deputized LHD for vaccinations.

Note: *Children whose health insurance covers the cost of vaccinations are <u>not</u> eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.*

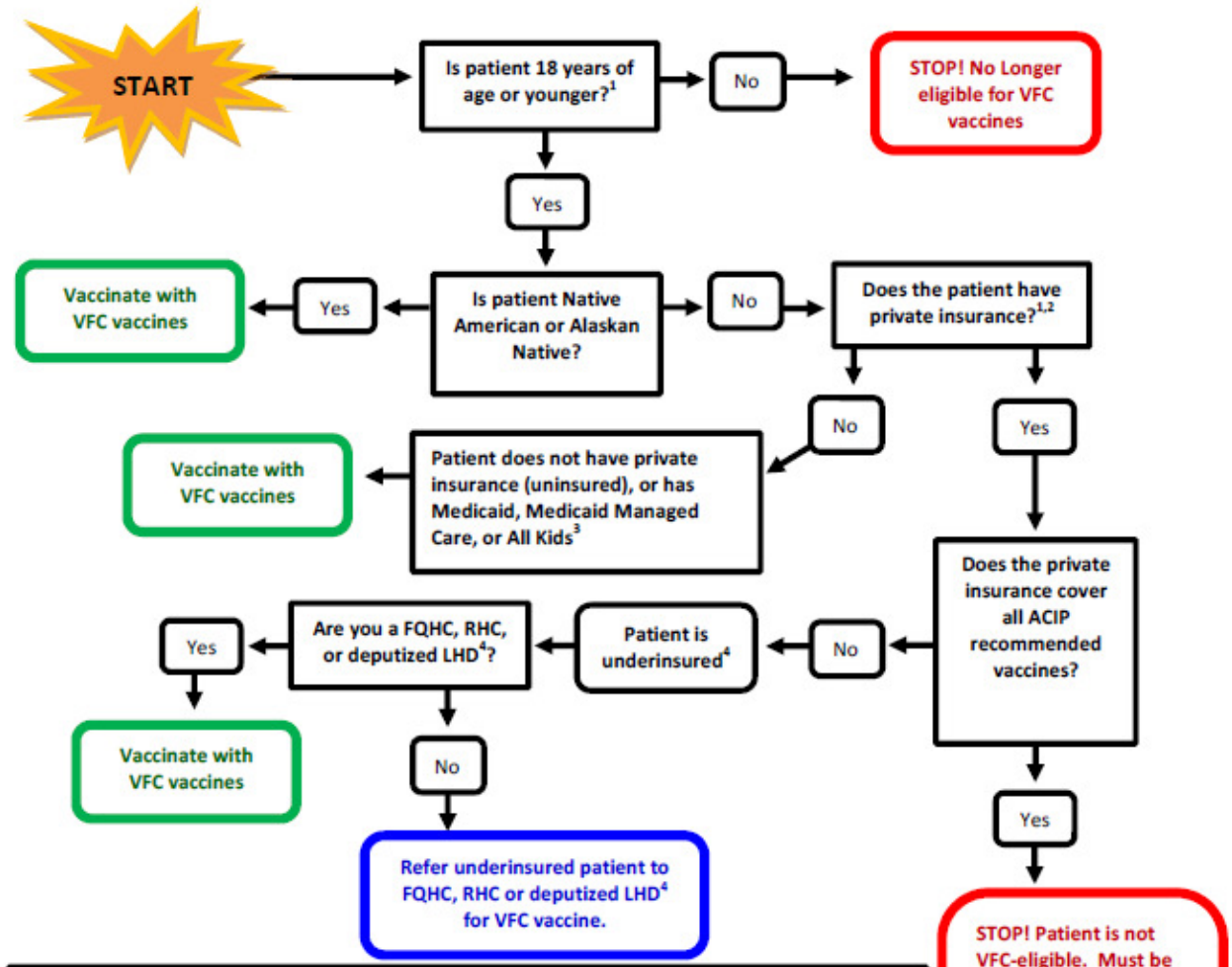
Please note: Underinsurance, limited coverage, and "caps" should be rare instances with the implementation of the Affordable Care Act (ACA).

TABLE 1: VFC ELIGIBILITY SCENARIO

Based on the Centers for Disease Control and Prevention's VFC Operations Guide.

VFC eligibility scenario: Child is insured and…	**Insurance Status**	**Is child VFC eligible?**
Has not yet met plan's deductible	Insured	**No, not VFC eligible**
Plan covers all ACIP recommended vaccines but excludes certain products/ combination vaccines	Insured	**No, not VFC eligible**
Plan covers only a portion of the vaccine cost and **does not** *have Medicaid as secondary insurance*	Insured	**No, not VFC eligible**
Plan has a high deductible	Insured	**No, not VFC eligible**
Has insurance, but plan limits coverage to a specific number of provider visits annually.	Underinsured (once the limited number of allowable visits are reached during the year)	**Yes, VFC eligible once the limited number of visits have been reached, but only through a FQHC, RHC or approved deputized provider**
Seeking contraceptive or sexually-transmitted disease (STD) services at school-based clinic or facility whose main services are primary or acute care and wants to be immunized but does not want to access insurance.	Insured	**No, not VFC eligible**
Seeking contraceptive or STD services at family planning clinic or STD clinic and wants to be immunized but does not want to access insurance or doesn't know status.	Uninsured	**Yes , VFC eligible**
Has Medicaid as secondary insurance	Medicaid eligible	**Yes , VFC eligible**
Plan covers only a portion of the vaccine cost **and** *has Medicaid as secondary insurance*	Medicaid eligible	**Yes , VFC eligible**
Has not yet met plan's deductible **and** *has Medicaid as secondary insurance*	Medicaid eligible	**Yes , VFC eligible**
Has exceeded plan's annually allowed number of provider visits	Underinsured	**Yes , VFC eligible but only through a FQHC, RHC or approved deputized provider**
Cannot access health insurance due to being incarcerated	Uninsured	**Yes , VFC eligible**
Children enrolled in Medicaid-expansion Children's Health Insurance programs	Medicaid eligible	**Yes , VFC eligible**
Children enrolled in a Medicaid program: Managed Care Organizations (MCOs), Managed Care Community Networks (MCCNs), Accountable Care Entities (ACEs), or Care Coordination Entities for Children with Special Needs (CSN CCEs).	Medicaid eligible	**Yes , VFC eligible**

VFC ELIGIBLE DECISION TREE



1 It is the responsibility of providers to screen patients to ensure that fully insured patients do not receive federally-supplied VFC vaccine. Providers should encourage patients to review insurance benefits when scheduling, have staff check benefits. If a patient arrives for an appointment and is still unsure of vaccine coverage, vaccination should be deferred until insurance coverage question(s) can be answered.

2 Patients who are 18 years of age and younger with Medicaid, either as primary or secondary insurance, are eligible to receive VFC vaccines.

3 In addition to traditional Medicaid coverage, Medicaid also has All Kids (the state's Child Health Insurance Program (CHIP) coverage), Managed Care Organizations (MCOs), Managed Care Community Networks (MCCNs), Accountable Care Entities (ACEs), or Care Coordination Entities for Children with Special Needs (CSN CCEs). Children with All Kids coverage should have their eligibility documented as "V06 VFC eligible - State specific eligibility." If the type of Medicaid coverage is not able to be determined, Medicaid eligibility may be documented as "V02 VFC eligible-Medicaid/Medicaid Managed Care." Contact the Illinois Department of Healthcare and Family Services (HFS) for any questions regarding Medicaid coverage at:

E-Mail: hfs.webmaster@illinois.gov **Internet:** http://www.hfs.illinois.gov/
HFS: 217-782-5565 **All Kids:** 800-804-3833
Provider Help Line: 800-804-3833

4 Underinsured children include those children whose insurance coverage does not include any vaccinations, OR does not allow all recommended vaccines, OR has coverage caps on the number of allowable provider visits, OR has caps at a certain dollar amount. Once those criteria are reached, the underinsured child can receive VFC vaccine only at a federally qualified health center, rural health clinic or a local health department deputized by a FQHC to serve the underinsured. These children are only underinsured for the vaccines not covered. ***Patients who have insurance with high deductibles are not underinsured.***

VFC ELIGIBILITY HIERARCHY

Providers must screen and document VFC eligibility at each immunization visit. Occasionally, children may be eligible for VFC vaccine in two different categories. Providers should always choose the option that requires the least amount of out-of-pocket expenses to the parent/guardian. Providers should always verify insurance coverage prior to administering vaccines.

The VFC program does not allow the borrowing of VFC vaccine. The VFC program cannot support a policy that permits borrowing of VFC vaccine for use in non-eligible children. Private vaccine used on VFC patients cannot be paid back using VFC vaccine. Similarly, VFC vaccine cannot be used in non-eligible children and then paid back with private stock. If VFC vaccine is unavailable, the provider should reschedule the child or refer the VFC eligible child to a local health department for vaccination.

MINORS AT FAMILY PLANNING CLINICS

Minors under 19 years of age who do not know their insurance status and who present at **family planning clinics for contraceptive services or sexually transmitted infection treatment** can be considered **uninsured** for the purposes of the VFC program. CDC defines a family planning clinic as a clinic or provider whose purpose is to prescribe contraceptives and/or treat sexually transmitted infections. *Note: VFC-enrolled providers whose main services are primary or acute care do not meet CDC's definition of a family planning clinic and cannot use this VFC eligibility category.*

A minor under 19 years of age who is seeking contraceptive or sexually-transmitted disease (STD) services at school-based clinic or facility whose main services are primary or acute care, wants to be immunized, and has insurance, but does not want to access insurance, is considered **insured and not eligible for VFC**.

Note: In Illinois, the state does not require parental consent for adolescents who wish to be vaccinated against hepatitis B and/or human papillomavirus (HPV). Local clinic and/or health department administrators may require consent under local agency guidance. However, CDC and the Department view consent as a possible barrier to vaccination. A vaccine information statement (VIS) must routinely be offered upon vaccination.

INSURED CHILDREN WITHOUT MEDICAID AS A SECONDARY INSURANCE

Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines, even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met. Privately insured children, even those without a medical home, cannot be vaccinated with VFC vaccine by any VFC provider site – even an FQHC or RHC. These children must be vaccinated with privately-acquired vaccine.

The following common scenarios do not qualify patients for access to VFC vaccine:

- Children whose insurance plans maintain high deductible rates that deny provider payment claims for the cost of the vaccine and its administration when the plan's deductible (high deductible plan) has not been met.
- Children whose insurance plans cover all ACIP-recommended childhood vaccines, but exclude certain combination vaccines or certain products. A child with this type of coverage would be considered insured and NOT eligible for VFC because all recommended vaccines are covered.

- Children whose insurance plans cover a portion of the cost of the vaccine, even though it may be only a small portion of the cost of the vaccine. These children are considered insured and NOT eligible for VFC vaccine.

FULLY INSURED CHILDREN WITH MEDICAID AS SECONDARY INSURANCE

Situations can occur where children have private health insurance that includes full immunization benefits and Medicaid as a secondary insurance. These children are VFC-eligible as long as they are enrolled in Medicaid. VFC is an entitlement program, and participation is not mandatory for an eligible child. **For children who have full immunization benefits through a primary private insurance, the decision to participate in the VFC program should be made based on what is financially most cost-effective to the child and his/her family.** The VFC program does not allow the borrowing of VFC vaccines. Providers cannot use private vaccine with VFC patients and expect to pay back private stock with VFC vaccine. Similarly, VFC vaccine cannot be used in non-eligible children and then expect to be paid back with private stock. **Providers should ensure private insurance will cover the vaccinations before vaccines are administered.**

Example 1:

For children whose primary health insurance does not cover immunizations, limits the types of vaccines, or caps immunization coverage to a certain financial amount AND who have Medicaid as secondary coverage:

- All providers should select Medicaid as the VFC-eligibility category, use VFC vaccine, and bill Medicaid for the administration fee.
- Even though the child meets the VFC definition for underinsured, it should not be selected because the child would be VFC eligible only through an FQHC/RHC, and the parent would be responsible for the VFC vaccine administration fee.
- By selecting Medicaid, the child is VFC-eligible in all VFC provider settings, and Medicaid is responsible for the reimbursement of the administration fee.

The parent would never be billed the administration fee since the child is enrolled in Medicaid.

Example 2:

A child should be screened for VFC eligibility as having Medicaid if the child is covered by a high-deductible insurance plan requiring the parent to pay out-of-pocket for vaccines until the deductible has been reached, AND the child has Medicaid as secondary insurance:

- The child should be considered VFC-eligible if the family has not reached its deductible yet. VFC vaccine should be administered, and the administration fee billed to Medicaid until the deductible is reached.

Example 3:

If a child has health insurance that covers only a portion of the cost of the vaccine and the child has Medicaid as secondary insurance:

- The child should be screened as having Medicaid and be considered VFC-eligible. VFC vaccine should be administered and the administration fee billed to Medicaid.

Note: *Please remember that these children in these examples are only VFC-eligible because they have Medicaid as secondary insurance coverage. If the child was enrolled in a high-deductible insurance plan, the family had not met the deductible yet, and had no secondary Medicaid, the child would be considered insured and not eligible for the VFC program. The same would apply to children covered by insurance that covers only a portion of the vaccine cost, and who have no secondary Medicaid; these children would be considered insured and not eligible for the VFC program.*

AI/AN WITH HEALTH INSURANCE THAT COVERS IMMUNIZATIONS

American Indian/Alaskan Native (AI/AN) children are always VFC-eligible. VFC is an entitlement program and participation is not mandatory for an eligible child. For AI/AN children who have full immunization benefits through a primary private insurance, the decision to participate in the VFC program should be made based on what is financially most cost advantageous to the child and family.

JUVENILES IN CORRECTIONAL FACILITIES

If a child under age 19 years loses access to their health insurance because of incarceration, the child is considered uninsured and VFC-eligible.

STATE OF RESIDENCY

At times, VFC-eligible children receive health care in a bordering state instead of their state of residency. Illinois providers enrolled in the VFC program may vaccinate children who are VFC-eligible, but reside in another state. Providers must be educated that if the provider administers VFC vaccine to a Medicaid VFC-eligible child from a neighboring state the provider must be a Medicaid enrolled provider for the state where the Medicaid VFC-eligible child resides in order to receive reimbursement for the administration fee from that state's Medicaid program.

PROVIDER RESPONSIBILITY TO SCREEN FOR VFC ELIGIBILITY

Screening to determine a child's eligibility to receive vaccines through the VFC program must take place with each immunization visit. The Patient Eligibility Screening Record developed by the Department provides a means of recording parent response to VFC eligibility questions. The provider, parent, or guardian may complete the VFC eligibility portion of the form. Verification of parent/guardian responses is not required. If providers elect not to use the Department's tool, a separate screening form must be used. Providers must correctly document VFC eligibility in I-CARE for each dose of vaccine administered.

Providers using electronic medical records (EMRs) to document* vaccinations must have the capability to enter VFC eligibility status, all of the criteria from the Patient Eligibility Screening Record, the eligibility in which the patient qualifies at each immunization visit, and vaccine lot numbers on a per dose basis.

** All VFC program related documentation, including eligibility screening, vaccine temperature log reports, and vaccine order documentation, must be retained for three years.*

MODULE 3: PROVIDER ENROLLMENT

All VFC providers must enroll in the VFC program on an annual basis. VFC providers are required to register to use the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE), a tool used by health care providers, parents, public health agencies, and schools to record and promote immunization records. The VFC program utilizes I-CARE for the VFC program.

Annual enrollment for the VFC program is submitted through I-CARE. Enrollment forms are completed in I-CARE with an enrollment confirmation page to be signed and faxed or e-mailed to the Department, along with certificates of calibration for all thermometers.

Providers who are new to the VFC program will need to complete the I-CARE application first. Information and forms for enrollment in I-CARE are available at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/icare. Providers may contact the I-CARE team at DPH.ICARE@illinois.gov to check the status of an I-CARE enrollment application.

PROGRAM PARTICIPATION OVERVIEW

Requirement	Description
Designation of key clinical staff	VFC providers must designate a vaccine coordinator and at least one backup vaccine coordinator(s) who will both be fully trained to oversee and manage the clinic's vaccine supply. The VFC program prefers to have an office manager, RN, NP, PA, or MD as the primary vaccine coordinator. The contact name and information for each vaccine coordinator must be current in the clinic's profile in I-CARE. Any personnel changes in this role must be immediately reported to the VFC Program through the "contact us" link in I-CARE.
Completion of VFC educational requirements	Each VFC vaccine coordinator is required to complete and maintain documentation of receiving annual VFC education on vaccine storage and handling. Education is available through VFC compliance site visits, VFC trainings, or through CDC online training, "You Call The Shots – Module 10 – Storage and Handling," available at http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp. We recommend two modules for VFC providers: "Vaccines For Children (VFC)-2015" and "Vaccine Storage and Handling-2015." You will need to register for continuing education credits to receive a certificate of completion. Training should also be documented in the Vaccine Management Plan on the training log.
VFC Eligibility Screening & Documentation	Screening for VFC eligibility must occur with all clinic patients 0 through 18 years of age, prior to vaccine administration and must have VFC eligibility screening documented in the patient's permanent medical record (paper-based or electronic medical record) **at each immunization encounter**. Eligibility documentation must be kept in the patient's medical record for three years. Documentation of eligibility screening must include the following elements: • Date of screening • Whether the patient is VFC eligible or not VFC eligible • If VFC eligible, the eligibility criteria the patient met The VFC Eligibility Screening Form is available in I-CARE. Patients who are 18 years of age and younger with Medicaid, either as primary or secondary insurance, are eligible to receive VFC vaccines. In addition to traditional Medicaid coverage, Medicaid also has managed care option plans (MCO) and All Kids, which

	is the state's Child Health Insurance Program (CHIP). Children with any Medicaid coverage are VFC eligible. Children with All Kids coverage should have their eligibility documented as V06 (VFC eligible - State specific eligibility). If the type of Medicaid coverage is not able to be determined, Medicaid eligibility may be documented as V02 (VFC eligible-Medicaid/Medicaid Managed Care). Contact the Illinois Department of Healthcare and Family Services (HFS) for any questions regarding Medicaid coverage at: • E-Mail: hfs.webmaster@illinois.gov • Internet: http://www2.illinois.gov/hfs/Pages/default.aspx • HFS: 217-782-5565 • Provider Help Line: 800-804-3833 • All Kids: 800-255-5437 HFS distributed an informational notice on June 24, 2014 that provides an overview of the Medicaid Managed Care plans and lists detailed information for each region in Illinois. The memo, "REVISED – Care Coordination Enrollment for Children, Families and ACA Adults" from June 24, 2014, is available at the HFS website at http://www.hfs.illinois.gov/all/2014.html.
VFC Vaccine Administration Fees	VFC providers may charge VFC-eligible children **not** covered by Medicaid a vaccine administration fee up to $23.87 per dose (not antigen) of vaccine. VFC providers may not exceed the federal maximum administration fee nor may they charge non-Medicaid VFC-eligible children for the cost of the vaccine.
Vaccine Ordering and Accountability	Adequate vaccine supply must be maintained in accordance with practice patient population. Providers should maintain enough VFC inventory for at least five (5) weeks but should not exceed three (3) months. VFC vaccine supply and private vaccines should be kept separate and clearly labeled to allow easy identification and to prevent misuse of VFC vaccines on ineligible patients. All VFC documentation, including temperature logs, are required to be kept for a period of at least three (3) years. All VFC providers must report patient immunization records in I-CARE on the administration of VFC vaccines. The patient-level data may either be directly entered into I-CARE or providers may work with their EMR vendor to have data electronically transferred. If you need assistance with your electronic transmission, click on "Contact Us" in I-CARE and select "HL7" as the category.
Thermometers	Providers are required to have a thermometer in each unit, with at least one back-up thermometer available on-site. CDC recommendation is for the use of a digital data logger thermometer with a detachable probe in a buffered material (e.g., glycol) with continuous monitoring capabilities. The temperature should be easily readable from the outside of the unit. Additional recommended features include: • Alarm for out-of-range temperatures • Current, minimum and maximum temperatures • Low battery indicator • Accuracy of +/- 1°F (0.5°C) • Memory stores at least 4,000 readings; device will not write over old data – stops recording when memory is full • User programmable logging interval (or reading rate)
Thermometer Calibration & Certification	Primary and back-up thermometers must have a certification of calibration that is current (no more than two years since last calibration testing or based on the manufacturer's recommended re-testing timeline). A valid certification of calibration must be kept on file and be readily available for review during VFC visits. Calibration should be conducted by an ILAC/MRA accredited laboratory.

	• **Calibration certificates from an ILAC/MRA accredited laboratory must include:** ☐ Model number ☐ Serial number ☐ Date of calibration (report or issue date) ☐ Measurement results indicate unit passed testing: This may be listed under "Pass/Fail," "In Tolerance," or "In Tol." ☐ The documented uncertainty is listed and within suitable limits (recommended uncertainty = +/- 1F or 0.5 C): This may be listed under "Uncertainty," "±U," or "+/-." • **Calibration certificates from non-accredited laboratories must include:** ☐ Name and address of laboratory conducting testing ☐ Model number ☐ Serial number ☐ Date of calibration (report or issue date) ☐ Measurement results indicate unit passed testing: This may be listed under "Pass/Fail," "In Tolerance," or "In Tol." ☐ Statement of conformance with ISO/IE17020 calibration procedure standards Thermometers that are no longer accurate within +/-1 F (+/-.5 C) as indicated in calibration measurement results must be replaced. **Additional Information** • If your certificate(s) of calibration does not have all of the required items, please contact the manufacturer of the thermometer (or whoever did the calibration testing) to see if they will reissue the certificates. Several manufacturers are willing to reissue certificates to include the missing items. • If you need to purchase new thermometers, please contact the company and ask them to provide you with a sample of their certificate of calibration so you can see if all of the required items are listed before you purchase the thermometers. If you would like for IDPH to review a sample certificate, please email it to DPH.Vaccines@illinois.gov. Please be sure to include your VFC PIN on all communication. • If your certificate of calibration does not have an expiration date specified, the VFC program will allow an expiration date of no longer than two years from the date calibration testing was performed.
Temperature Monitoring	Temperatures for each unit must be read and documented twice each workday, at least three days a week, at the beginning of the day and prior to closing. Additionally, minimum and maximum temperatures are recommended to be read and documented at the beginning of each workday. Temperature logs are required to be maintained for three years. Temperatures should be recorded in I-CARE on a weekly basis. The VFC program strongly recommends clinics that are routinely closed for more than 2 consecutive days and do not have staff that assess and record temperatures twice a day on days when the office is closed, use a continuous monitoring and recording digital data logger with downloadable capabilities and the characteristics listed above. **CDC requires that temperature documentation (including hard copy paper temperature logs) contain (1) at least two temperature readings per day, (2) the time and date of each reading, and (3) the name (or initials) of the person who assessed and recorded the readings.** Temperature logs in both Celsius and Fahrenheit are available in I-CARE on the home page under "Immunization Links" and at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/vfc-program.

Borrowing	The VFC program does not allow the borrowing of VFC vaccine. The VFC program cannot support a policy that permits borrowing of VFC vaccine for use in non-eligible children. Providers will no longer be able to borrow private vaccine and expect VFC to pay back their private stock, nor may providers borrow VFC vaccine to use in non-eligible children and then pay back VFC with private stock.
Vaccine Transfers & Returns	**Transfers** Ordered vaccines must be shipped and stored at the facility indicated on the clinic profile on the enrollment forms and in I-CARE. VFC vaccines may be transferred in limited situations and only to other VFC-enrolled providers. It is the provider's responsibility to find another VFC provider willing to accept the vaccine. VFC providers must receive pre-approval for transfers. The transfer approval request form is available in I-CARE on the home page under "Immunization Links" and at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/vfc-program. Please allow 10 business days for your request to be reviewed and receive approval. Transfer of vaccines should only occur for the following reasons: • Vaccine is six months or less from expiration date and unable to be used by provider prior to expiration date. • An area outbreak has resulted in unexpected surge of walk-in patients. • Clinic closure requiring redistributing vaccines to other VFC providers. • Seasonal clinic needing to transfer vaccine to other VFC providers at end of time facility will be open. Providers may not transfer influenza vaccine. IDPH will evaluate requests to transfer frozen vaccines on a case-by-case basis to ensure providers have the appropriate equipment. **Expired (Returned to McKesson) and Wasted (Not Returned to McKesson) Vaccines** VFC providers must record all expired and wasted vaccine doses in I-CARE so that expired vaccines may be returned to the vaccine distributor for excise tax credit. Expired vaccines must be return within six months of the expiration/spoilage date. Providers may not use the wasted (not returned to McKesson) transaction to balance their inventory. Providers reporting excessive expired or wasted vaccines may be responsible for replacing those vaccines according to the Vaccine Loss and Replacement Policy.
Site Visits	Actively enrolled VFC providers agree to VFC program site visits, which may include compliance visits, unannounced storage and handling visits, or educational site visits. Unannounced storage and handling visits serve as spot checks to ensure VFC supplied vaccines administered to VFC-eligible children are managed and stored according to program requirements. Any active VFC provider may be chosen to receive an unannounced storage and handling visit.
Vaccine Management Plan	All VFC providers are required to have a Vaccine Management Plan and to review it annually or more often if staff changes. The Vaccine Management Plan template is available in I-CARE on the home page under "Immunization Links.".

ENROLLMENT

All VFC providers are required to submit an annual enrollment to continue in the VFC program. Annual enrollment must be submitted and approved by January 1st of the year or the provider's ordering privileges will be suspended. Enrollment documentation is available in and submitted through I-CARE.

Providers will need to read and agree to the following policies, which are available in I-CARE and updated annually:

- VFC Enrollment Agreement Terms
- VFC Provider Enrollment Policy
- VFC Loss and Replacement Policy

Provider agreement forms must be signed annually by the medical director or the equivalent in a group practice. The health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law. The practitioner will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the Provider Enrollment Agreement.

All licensed health care providers in the enrolled practice – and their corresponding professional license numbers - must be listed on the provider agreement form.

According to Section 1928 (c) (1) (A) of the Social Security Act (42 U.S.C. 1396s (c) (1) (A) the following providers qualify to be VFC program-registered providers:

> Health care providers "licensed or otherwise authorized for administration of pediatric vaccines under the law of the State in which the administration occurs" (subject to section 333 (e) of the Public Health Service Act, which authorizes members of the Commissioned Corps to practice).

The CDC Provider Agreement form represents the provider's agreement to comply with all the conditions of the VFC program, as well as ensuring that the practice/clinic/facility and all providers listed on the agreement will adhere to the requirements of the program.

Please refer to I-CARE for detailed instructions on the enrollment procedure.

MEMORANDUM OF UNDERSTANDING (MOU) WITH A FQHC OR RHC

LHDs who wish to qualify to vaccinate underinsured children using VFC vaccine must be established and recognized as a FQHC, RHC or an agency with FQHC delegate authority. A FQHC can use a memorandum of understanding (MOU) (request from the IDPH VFC administrator) to delegate authority to certified LHDs who are not an FQHC with a Health Resources and Services Administration PHS Section 330 grant award notice or an RHC with a Department RHC status letter and participate in the Illinois VFC program to vaccinate underinsured children on their behalf. Providers should retain a copy of their MOU and submit it annually during VFC re-enrollment to continue to be able to administer VFC vaccine to underinsured patients. LHDs are not required to complete a new MOU unless the Medical Director at the LHD has changed. A change in administrator at the LHD, FQHC, or IDPH does not require the completion of a new MOU. For more information on deputization agreements, please contact the VFC administrator at Linda.Kasebier@illinois.gov or 217-785-1455.

VFC ENROLLMENT VISITS

All providers newly enrolling or re-enrolling after an absence in the VFC program must have an enrollment site visit. The purpose of this visit is to ensure that providers and provider office staff are educated on the VFC program requirements and have appropriate resources to implement program requirements. The enrollment visit will include the following content:

- Review and confirm provider and staff understand and are able to implement the requirements of the VFC program as outlined on the VFC Provider Enrollment Policy.
- Review of all VFC requirements and confirmation of the provider's understanding
- Confirmation that the provider knows who to contact if problems arise, specifically with storage and handling issues

A VFC unannounced storage and handling may be conducted approximately six months after the provider begins receiving VFC vaccine.

EDUCATION REQUIREMENT

Each VFC vaccine coordinator is required to complete and maintain documentation of receiving annual VFC education on vaccine storage and handling. Education is available through VFC compliance site visits, VFC educational visits, regional VFC trainings offered through the Department partners (ICAAP or EverThrive) or through CDC online training, "You Call The Shots – Module 10 – Storage and Handling," available at http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp. Additional online training will be available soon through the Illinois Chapter of American Academy of Pediatrics at http://illinoisaap.org/. A VFC Training Log is available in the Vaccine Management Plan for providers to document training.

TERMINATION OF ENROLLMENT AGREEMENT

IDPH or the provider may terminate this agreement at any time or if there is failure to comply with these requirements. If the agreement is terminated, the provider agrees to properly return any unused VFC vaccine within 30 days of the termination date. See the VFC Program Withdraw form at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/vfc-program.

MODULE 4: VACCINE MANAGEMENT

Vaccine management is a broad term intended to describe the storage and handling practices that should be followed by all VFC providers. While the vaccine management practices here specifically only applies to VFC vaccines, we recommend providers consider the VFC vaccine management as a best practice for their private vaccine inventory as well.

The CDC Vaccine Storage and Handling Toolkit provides guidance and best practices for all health care providers (including VFC-enrolled providers) and is available at http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf.

VACCINE COLD CHAIN

The vaccine cold chain is a system or process used to maintain vaccines at optimal conditions. Vaccines must be stored properly from the time they are manufactured until the time they are administered to ensure those who receive the vaccines are protected from disease. Excess heat or cold will reduce vaccine potency and increase the risk that recipients will not be protected. All VFC vaccine storage and handling requirements and recommendations are in place to ensure the cold chain is maintained.

RECEIVING AND UNPACKING VACCINE SHIPMENTS

Upon receipt of a vaccine shipment, providers must:

- Open vaccine packages immediately
- Check the temperature monitor readings
- Inspect the vaccine and packaging for damage
- Determine length of time the vaccine was in transit by looking at the packing list
- Compare the vaccine received with the vaccine products that appear on the packing list
- Immediately store at appropriate temperatures

All staff who accepts vaccine deliveries must be instructed on the importance of maintaining the "cold chain." Vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold will reduce their potency and increase the risk that recipients will not be protected.

When the vaccine is received by front desk personnel, the vaccine coordinator or back-up vaccine coordinator must be notified immediately. The box should be taken to the storage area and unpacked in the following manner:

1. Open the shipping container immediately upon delivery and examine the contents for signs of physical damage, and possible out of range temperatures.
2. **WITHIN TWO HOURS OF VACCINE DELIVERY: If any damage, excessive shipping time, or cold chain breach has occurred, provider must IMMEDIATELY call the Department's Immunization Promotion Center (IPC) at 217-786-7500.**
    - If the provider does not call the Department within two (2) hours of the vaccine delivery to report discrepancies and/or cold chain issues, this constitutes provider negligence in accordance with the Vaccine Loss and Replacement Protocol due to handling and storage mishaps by provider staff. Shipments that result in vaccine loss negatively impact the Illinois VFC vaccine budget.

- When calling IDPH about a vaccine delivery: Expect that staff will have to report on temperature indicators if anything is wrong (cold chain breach indicated). A questionnaire will be completed with Illinois VFC program and CDC/manufacturer to determine viability. Provider staff should store the vaccine appropriately and maintain the shipment packing list. Ensure that temperature logs are maintained for the vaccine in question. IDPH, CDC, and/or McKesson Specialty MAY ask for this paper work.

3. With each vaccine delivery, check the actual vaccines received against the shipping invoice to verify all vaccines were received. Compare the original order against what was received. **If there is a discrepancy with the order, contact the Illinois VFC program within two (2) hours at 217-786-7500.**
4. Make sure diluents that accompany MMR, MMRV, and Varicella match the amount of vaccine received.
5. Place the new vaccines into the refrigerator and/or freezer immediately with the shortest expiration dates in the front of the pack. Separate the VFC vaccines from the private supply by tagging the VFC vaccines and placing them in a separate labeled area of the refrigerator and/or freezer. Vaccines should be kept in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type.
    - Store refrigerated diluents with corresponding vaccine (these diluents may contain vaccine antigen).

DAY-TO-DAY VACCINE MANAGEMENT

The following are recommended practices for providers handling vaccines:

- Store vaccines in their original packaging
- Store vaccines in the middle of the unit, with space between both the vaccines and the side/back of the unit.
- Do not store vaccines in the doors, vegetable bins, or floor of the unit, or under or near cooling vents.
- Do not store food or drink in vaccine storage units.
- Place water bottles throughout the refrigerator and frozen coolant packs in the freezer storage units in order to:
    - Stabilize or extend temperatures during a power outage,
    - Help to mitigate the effects of frequent open/closing door during busy clinic days, and
    - Serve as physical blocks preventing the placement of vaccines in areas of the unit that are at higher risk for temperature excursions.
- Rotate vaccine every week or when a new shipment comes in (whichever happens more frequently) so that newer vaccines are stored toward the back of the unit, while those soonest-to-expire are stored in the front.
- Open only one vial or box of a particular vaccine at a time to control vaccine use and allow easier inventory control. On each opened vaccine vial, indicate on the label the date and time it was reconstituted or first opened.
- Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.
- Limit access to the vaccine supply to authorized personnel only.
- Install locks on refrigerators and, if possible, the electrical plug.
- Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.

- In larger clinics, provide a source of back-up power (generator) and a security system to alert appropriate personnel in the event of a power outage.
- If applicable, test back-up generators quarterly and maintain back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).
- In regular clinics/practices, vaccines should be prepared immediately prior to administration. CDC strongly recommends NOT pre-drawing doses before they are needed.

BORROWING VACCINES

VFC-enrolled providers are expected to maintain adequate inventories of vaccine for their privately insured and VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider's privately-purchased vaccine inventory. The provider must ensure their VFC vaccine supply is adequate to meet the needs of the provider's VFC-eligible patients.

The VFC program does not allow the borrowing of VFC vaccine. The VFC program cannot support a policy that permits borrowing of VFC vaccine for use in non-eligible children. Private vaccine used on VFC patients cannot be paid back using VFC vaccine. Similarly, VFC vaccine cannot be used in non-eligible children and then paid back with private stock. If VFC vaccine is unavailable, the provider should refer the VFC eligible child to a local health department or FQHC or reschedule the child.

EQUIPMENT TYPES

Vaccine must be stored in one of the following equipment types:

A. Stand-alone refrigerator
B. Stand-alone freezer
C. Combination refrigerator/freezer- using only the refrigerator compartment for vaccine storage
D. Pharmaceutical/medical/laboratory grade refrigerator
E. Pharmaceutical/medical/laboratory grade freezer
F. Compact (under counter) refrigerator
G. Compact (under counter) freezer

CDC recommends the use of stand-alone refrigerator and freezer units, meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit.

In addition, frost-free or automatic defrost cycle units are preferred. **Because freezing of refrigerated vaccines affects vaccine potency more than other exposure problems, it is especially important that refrigerators be selected and set up to minimize the chance of freezing vaccine.** Providers should aim for maintaining refrigerator temperatures at 40 F or 5 C.

While use of stand-alone units is a best practice, an alternative to stand-alone units is using only the refrigerator compartment of a combination household refrigerator/freezer unit to store refrigerated vaccines. In this case, the combination household refrigerator/freezer should have separate exterior doors and thermostat controls for the refrigerator and freezer sections.

A separate stand-alone freezer should then be used to store frozen vaccines, since studies conducted by the National Institute for Standards and Technology (NIST) have demonstrated that the freezer section of combination units is not capable of reliably maintaining appropriate frozen vaccine storage temperatures.

VFC vaccines cannot be stored in dormitory-style refrigerators at any time.

Dormitory-style refrigerators are not allowable to store VFC vaccine at any time, even for temporary storage. Dormitory-style refrigerators do not maintain proper temperatures and pose a high risk of freezing vaccine. Any VFC vaccines found to be in dormitory-style refrigerators will be wasted and providers will be expected to replace the wasted VFC vaccine with privately-purchased vaccine. See the CDC Storage and Handling Toolkit at http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf for additional information.

CDC does not recommend storage of any vaccine in a dormitory-style (or barstyle) combined refrigerator/freezer unit under any circumstances. A dormitory-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. Some dormitory-style units may be sold as medical grade units, but may still be classified as dormitory-style due to having one exterior door with a freezer compartment located inside the refrigerator section.

The 2009 NIST research concluded that "the dorm-style refrigerator is NOT recommended for vaccine storage under any circumstance." In performance testing, the dormitory-style refrigerator demonstrated consistently unacceptable performance, regardless of where the vaccine was placed inside the unit. This type of unit exhibited severe temperature control and stability issues. Large spatial temperature gradients confirmed there is no "good" vaccine storage area in this style unit. Dormitory-style (or bar-style) units pose a significant risk of freezing vaccine even when used for temporary storage. Note that the use of dormitory-style units for storage of VFC vaccines or other vaccines purchased with public funds is prohibited. Compact, purpose-built storage units for biologics are available that are not considered to be dormitory-style or bar-style.

The following examples are considered dormitory-style refrigerators and are NOT allowable to store VFC vaccines at any time.

EQUIPMENT SIZE

Any refrigerator or freezer unit used for vaccine storage must be able to maintain vaccine storage temperatures year-round, be large enough to hold the year's largest inventory, be dedicated only to the storage of vaccines, and must have a certified calibrated thermometer inside each compartment used for storing vaccine.

VFC providers receive vaccine at no cost to them. However, the vaccines received are purchased with millions of taxpayer dollars. To reduce waste and spoilage of expensive vaccines, the VFC program has guidelines for vaccine storage units.

Office Size	**Recommended Equipment Size**
Very High Volume 10,000 doses/year	Pharmacy-grade or biologic-grade refrigerator-only units and stand-alone freezer units
High Volume 2,000-10,000 doses/year	Refrigerator-only (16.7 cubic feet minimum) and stand-alone freezer units
Medium Volume 500-2,000 doses/year	Refrigerator-only (16.7 cubic feet minimum) and stand-alone freezer units OR Pharmacy-grade or biologic-grade under the counter units
Low Volume Less than 500 doses/year	

TEMPERATURE MONITORING

Refrigerated vaccines must be maintained between 35 F and 46 F (between 2 C and 8 C) and frozen vaccines between -58 F and 5 F (between -50 C and -15 C) at all times. See the temperature range diagram on the following page.

Vaccine manufacturers set vaccine temperature requirements for storage. It is important to follow manufacturer vaccine product specifications found in the package insert. The package insert describes the required storage conditions for a particular vaccine.

Manufacturers have access to internal (unpublished) thermostability data concerning the impact of exposures to inappropriate temperatures or light for each vaccine lot. Any time the vaccines are exposed to temperatures outside the required ranges, providers must complete a Vaccine Incident Report (available in I-CARE or at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/vfc-program) and contact the vaccine manufacturers to determine vaccine viability.

Acceptable Temperatures for Vaccines

CERTIFIED CALIBRATED THERMOMETERS

The recommended method to ensure a refrigerator or freezer is maintaining the proper temperature for vaccine storage is to check and record the temperature at least twice a day each workday, preferably at the start and end of the workday, and no fewer than three times a week. The office must adhere to the following guidance:

- Each refrigerator and freezer must have a calibrated working thermometer certified in accordance with the National Institute of Standards and Technology (NIST) or a laboratory recognized by NIST, placed in a central area inside each compartment used for storing vaccine.
- VFC providers are required to have at least one back up thermometer with a current certificate of calibration on hand (not stored in unit alongside current thermometer). It should be available in case a thermometer in use is no longer working appropriately or calibration testing of the current equipment is required.
- Calibration testing of thermometers must be performed at least every two years from the last calibration testing date (date certificate issued).
- Handwritten temperature logs and I-CARE temperature logs must have the time of the reading and initials of the provider staff recording the temperatures.
- Record temperatures in I-CARE at minimum weekly.
- Record thermometer calibration information in I-CARE, including the date calibration certification is due.

The VFC program strongly recommends that clinics that are routinely closed for more than 2 consecutive days, and do not have staff assess and record temperatures twice a day on days when the office is closed, use the current CDC guidance for temperature monitoring equipment. CDC recommends use of a continuously monitoring and recording digital data logger with downloadable capabilities and the characteristics listed below.

The VFC program recommends use of a digital data logger thermometer with a detachable probe in a buffered material (e.g., glycol) with continuous monitoring capabilities. The temperature should be easily readable from the outside of the unit. Additional recommended features include:

- A detachable probe in a buffered material;
- Provides current, minimum and maximum temperatures that are easily readable from the outside of the unit;
- Alarm that actively notifies the provider of out-of-range temperatures;
- Viewable Low battery indicator;
- Capability of +/- 1°F (0.5°C) accuracy;
- Provides memory storage of at least 4,000 readings;
- Provides capability to not write over old data – stops recording when memory is full; and
- Equipped with user programmable logging interval (or reading rate)

Because a major risk factor affecting potency of refrigerated vaccines is exposure to freezing temperatures, it is important and recommended that glycol-encased probes are placed in the same area where the vaccine is stored. Vaccine and temperature monitors should be located in the central area of the storage unit where appropriate temperatures are best maintained.

Providers are responsible for maintaining current Certificates of Traceability and Calibration Testing.[1] Calibration testing of thermometers must be performed at least every two years from the last calibration testing date (date certificate issued). Provider must keep the certificate of calibration for each thermometer and back-up thermometer, and make them available for inspection during site visits.

The VFC program will allow calibration testing and traceability to be performed by a laboratory accredited by an ILAC MRA signatory body OR, as an alternative, by a laboratory or manufacturer that provides documentation that demonstrates calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability. **Between the two options, CDC recommends testing be performed by ILAC accredited laboratories.** An ILAC MRA accredited laboratory is the easiest way to identify the instrument has been tested correctly according to international standards.

A Certificate of Traceability and Calibration Testing (also known as a Report of Calibration) must include key pieces of information. Information required on the certificate depends on whether the laboratory performing calibration testing is an accredited or non-accredited laboratory. Before sending your thermometer(s) for calibration, check with the calibration company to verify required information will be included on your certificate. Many companies will provide a sample certificate of calibration upon request.

The following checklist describes the items required to be on the certificate of calibration.

CHECKLIST FOR CERTIFICATE OF CALIBRATION REPORTS

A. If the certificate identifies calibration testing was performed by an ILAC accredited laboratory:

- ILAC accredited laboratories are:

Tip: Look on the certificate for the laboratory name or logo

ILAC/MRA Signatory body accredited Laboratory

The Following Table lists the accredited laboratories

A2LA	L-A-B	ACLASS	IAS	PJLA	NVLAP
	LABORATORY ACCREDITATION BUREAU				

- The certificate of calibration must have these items:
  - ☐ Name of device (optional)
  - ☐ Model number
  - ☐ Serial number
  - ☐ Date of calibration (report or issue date)
  - ☐ Measurement results indicate unit passed testing: This may be listed under “Pass/Fail,” “In Tolerance,” or “In Tol.”
  - ☐ The documented uncertainty is listed and within suitable limits (recommended uncertainty = +/- 1F or 0.5 C): This may be listed under “Uncertainty,” “±U,” or “+/-.”

[1] Certificate of Traceability and Calibration Testing (also known as Report of Calibration) is a certificate that informs the user of a thermometer’s level of accuracy compared to a recognized standard based on testing by the National Institute of Standards and Technology (NIST).

B. If certificate does not identify an accredited laboratory

- These manufacturers or laboratories must provide a Certificate of Traceability or Report of Calibration Test that must include the following elements:
  - ☐ Name of device (optional)
  - ☐ Model number
  - ☐ Serial number
  - ☐ Date of calibration (report or issue date)
  - ☐ Measurement results indicate unit passed testing: This may be listed under "Pass/Fail," "In Tolerance," or "In Tol."
  - ☐ The documented uncertainty is listed and within suitable limits (recommended uncertainty = +/- 1F or 0.5 C): This may be listed under "Uncertainty," "±U," or "+/-."
  - ☐ Statement that calibration testing conforms to ISO 17025

If you already have calibrated thermometers and were advised that your certificate of calibration does not have all of the required items, please contact the manufacturer of the thermometer (or whoever did the calibration testing) to see if they will reissue the certificates. Several manufacturers have indicated they are willing to reissue certificates to include the missing items.

If you need to purchase new thermometers, please contact the company and ask them to provide you with a sample of their certificate of calibration so you can see if all of the required items are listed before you purchase the thermometers. If you would like for IDPH to review a sample certificate of calibration, please email it to DPH.Vaccines@illinois.gov. Please be sure to include your VFC PIN on all communication.

If your certificate of calibration does not have an expiration date specified, the VFC program will allow an expiration date of no longer than two years from the date calibration testing was performed.

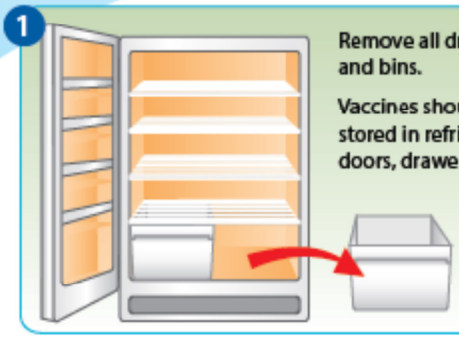
VACCINE REFRIGERATOR SETUP

Please see the following diagrams for VFC vaccine refrigerator setup.

Vaccine Refrigerator Setup

Preparing for Vaccine Storage

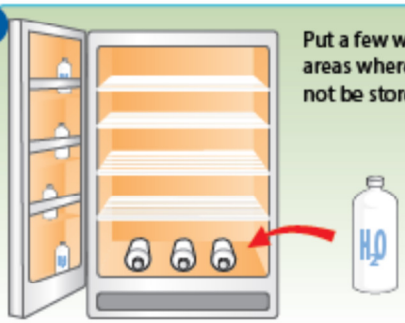
1



Remove all drawers and bins.

Vaccines should not be stored in refrigerator doors, drawers, or bins.

2



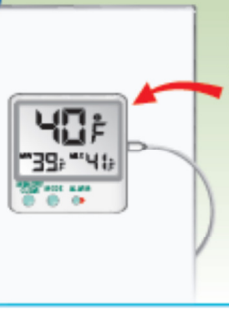
Put a few water bottles in areas where vaccines will not be stored.

3

Use a calibrated thermometer to ensure accurate temperatures. The thermometer must have a glycol-encased probe. The digital monitor must display CURRENT, MIN, and MAX temperatures.

Place the probe in the center of the refrigerator, near the vaccines.

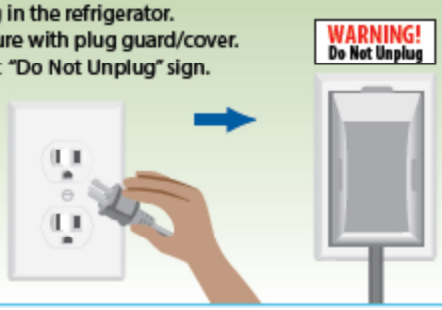
4



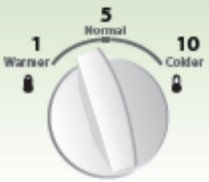
Attach the monitor to the outside of the refrigerator, either on the door or on the side.

5

Plug in the refrigerator.
Secure with plug guard/cover.
Post "Do Not Unplug" sign.



6



Set the refrigerator temperature.

If the refrigerator has a thermostat, set it for 40°F.

If it has a dial with a range of numbers, set it to slightly warmer than the middle of its range.

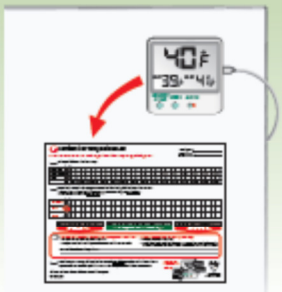
The next morning, check the temperature and adjust it until it stabilizes at approximately 40°F.

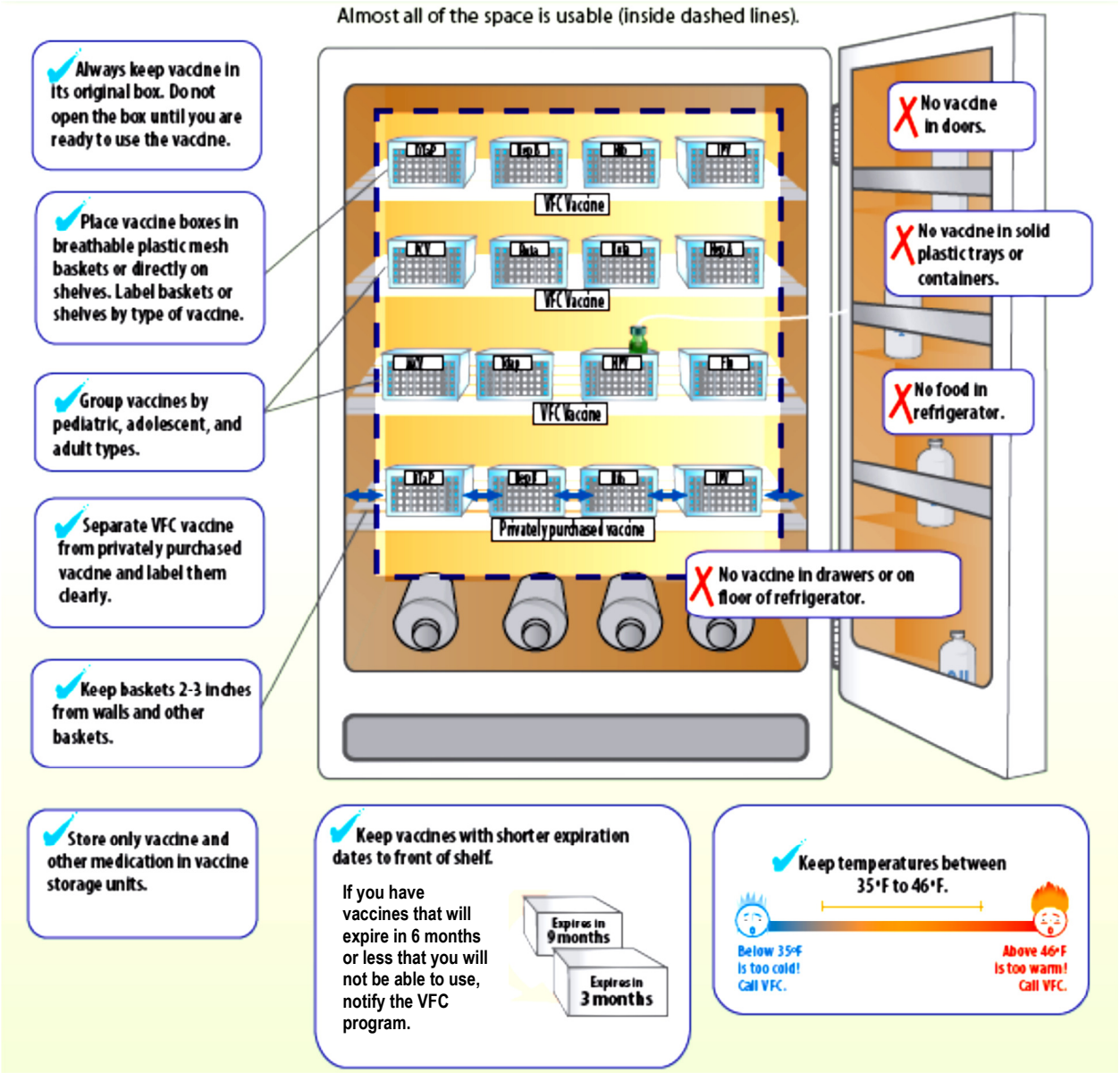
7

Once the temperature has stabilized, record it on the temperature log.

Record CURRENT, MIN, and MAX temperatures twice a day.

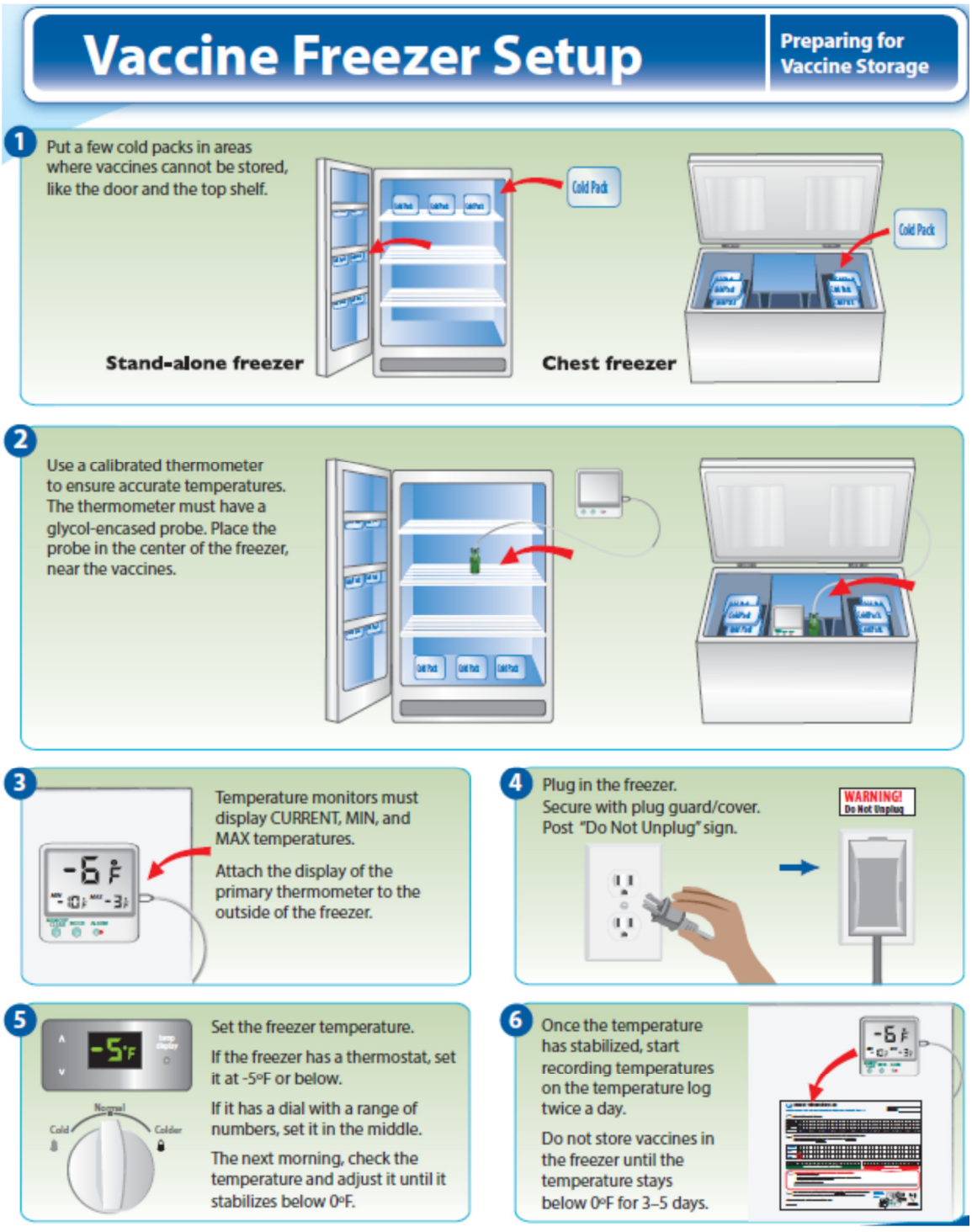
Do not store vaccines in the refrigerator until the temperature is stable at around 40°F for 3–5 days.




Almost all of the space is usable (inside dashed lines).
Always keep vaccine in its original box. Do not open the box until you are ready to use the vaccine.
Place vaccine boxes in breathable plastic mesh baskets or directly on shelves. Label baskets or shelves by type of vaccine.
Group vaccines by pediatric, adolescent, and adult types.
Separate VFC vaccine from privately purchased vaccine and label them clearly.
Keep baskets 2-3 inches from walls and other baskets.
Store only vaccine and other medication in vaccine storage units.
VFC Vaccine
VFC Vaccine
VFC Vaccine
Privately purchased vaccine
No vaccine in doors.
No vaccine in solid plastic trays or containers.
No food in refrigerator.
No vaccine in drawers or on floor of refrigerator.
Keep vaccines with shorter expiration dates to front of shelf.
If you have vaccines that will expire in 6 months or less that you will not be able to use, notify the VFC program.
Expires in 9 months
Expires in 3 months
Keep temperatures between 35°F to 46°F.
Below 35°F is too cold! Call VFC.
Above 46°F is too warm! Call VFC.

VACCINE FREEZER SETUP

Please see the following diagrams for VFC vaccine freezer setup.



✔ Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.

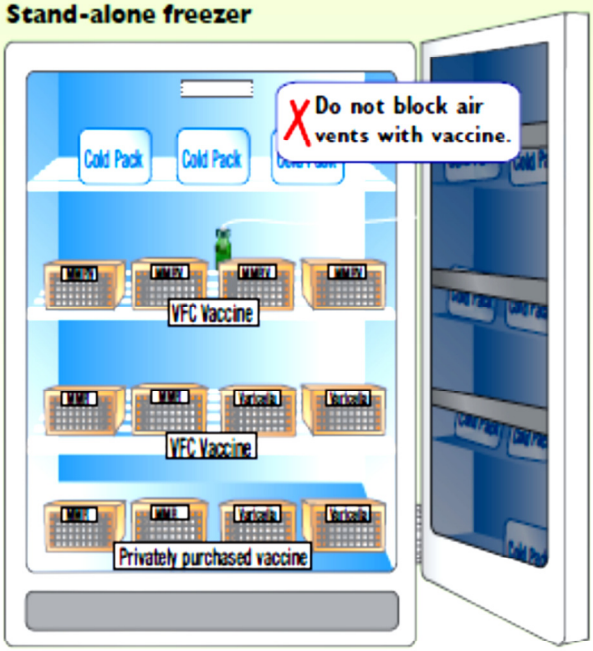
✔ Separate the VFC vaccine supply from privately purchased vaccine.

✔ Keep vaccines with shorter expiration dates to front of shelf.

If you have vaccines that will expire in 6 months or less that you will not be able to use, notify the VFC program.

✔ Keep temperatures 5°F or colder.

Stand-alone freezer



Chest freezer

VACCINE MANAGEMENT PLAN

All VFC providers must have a vaccine management plan on file that is reviewed and updated at least annually or when staff changes occur.

The Department has created a vaccine management plan template, which is available in I-CARE and at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/vfc-program, as a guideline for the protection and maintenance of the office's vaccine supply. The responsibilities listed in the vaccine management plan are those of the primary and back-up vaccine coordinators.

A copy of the Vaccine Storage and Emergency Response Plan must be posted on all refrigerators/freezers used to store VFC vaccines.

Office staff that handle or administer vaccines should be familiar with the vaccine management plan, which includes the vaccine storage and emergency response plan, and ensuring vaccines are maintained within the required temperature range.

The VFC program recommends that providers use the vaccine management plan template developed by the Department as it covers all required elements. Providers are able to create their own vaccine management plan, but it must include the following items.

- Name of the current primary vaccine coordinator and at least one back-up coordinator
- Signature, name, and title of the person completing the plan
- Date the plan was completed
- Contact information for individuals with 24-hour access to the building
- General operations for the following vaccine storage and handling practices:
  - ☐ Proper vaccine storage and handling practices
  - ☐ Temperature monitoring
  - ☐ Vaccine storage (e.g., equipment, placement)
  - ☐ Vaccine shipping and receiving procedures
  - ☐ Vaccine ordering procedures
  - ☐ Inventory control (e.g., stock rotation)
  - ☐ Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss)
  - ☐ Protocols for vaccine storage equipment maintenance
  - ☐ Protocols for the correct placement of vaccines within storage units
  - ☐ Protocols for responding to vaccine storage and handling problems
- Staffing
  - ☐ Descriptions of the roles and responsibilities of the primary and alternate (back-up) vaccine coordinators
  - ☐ Policy on education and training for facility staff
  - ☐ Staff training and documentation of training on VFC requirements, including proper vaccine storage and handling
- Emergency response plan:
  - ☐ The emergency response plan must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failure to vaccine storage units, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions.
  - ☐ Contact information for emergency storage locations.

- ☐ Contact information for refrigerator and freezer maintenance and repair companies.
- ☐ Contact information for vaccine storage unit alarm company (if applicable).
- ☐ Sources for packing materials, calibrated temperature monitoring devices, and portable refrigerator/freezer units or qualified containers.
- ☐ In addition, the plan must include policies and protocols for maintaining the vaccine cold chain during transport to and while stored in emergency storage locations.

MODULE 5: VACCINE LOSS AND REPLACEMENT

Vaccine accountability is a cornerstone of the Vaccines for Children (VFC) program and one of the program's highest priorities. Vaccine losses are absorbed directly by the VFC program's budget. Since the Illinois Department of Public Health (IDPH) VFC program is so important to the health and well-being of the children in Illinois, it is essential that all of us work together to ensure that every dose of vaccine is used to provide protection against preventable diseases. As a provider responsible for state-supplied vaccines, you and your staff should continually monitor vaccine storage and handling practices. Please notify the IDPH VFC program if you or your staff would like to receive an educational visit regarding vaccine storage and handling. VFC providers are required to report all wasted, expired, spoiled or lost vaccine to the Illinois VFC program.

The Vaccine Loss and Replacement Policy serves as the Department's policy for management of incidents that result in loss of state-supplied vaccine. Dose-for-dose replacement with privately-purchased vaccine for state-supplied vaccine may be required and provider's ordering privileges may be suspended until replacement is made.

DEFINITIONS

Wasted: Any vaccine that cannot be used. This includes expired, spoiled and lost vaccines.

Expired: Any vaccine with an expiration date that has passed.

Spoiled: Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Always consult with the vaccine manufacturer and Illinois VFC program before determining that the vaccine is spoiled or non-viable.

Lost: Commercial carrier (FedEx or UPS) or United State Postal Service (USPS) does not deliver the vaccine or does not deliver in a timely manner. This includes VFC vaccines the provider cannot locate, account for, thrown away, or disposed of against VFC policies.

SITUATIONS REQUIRING VACCINE REPLACEMENT

Below is a list of situations that require dose-for-dose replacement with privately-purchased vaccines.

EXPIRED VACCINE

- Failure to rotate or attempt to transfer vaccine that results in expired vaccine.
- Provider orders of vaccines that exceed the provider profile on file which results in excessive expired inventory.

SPOILED VACCINE

- Pre-drawn vaccine that is not used. Please note the Illinois VFC program strongly discourages the practice of pre-drawing vaccine.
- Handling and storage mishaps by provider staff.
- Vaccine that is left out of the refrigerator or freezer and becomes non-viable. Call the vaccine manufacturer first to help you determine the stability/viability of vaccine left out of the refrigerator/freezer.

- Vaccine stored in dorm-style refrigerators.
- Freezing vaccine that is supposed to be refrigerated.
- Refrigerating vaccine that is supposed to be frozen.
- Refrigerator/freezer left unplugged.
- Refrigerator/freezer door left open or ajar.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the Illinois VFC program within 30 days from the date you became aware of the situation.
- Power outages in which the provider fails to follow the facility's Vaccine Storage and Emergency Response Plan.
- Vaccine that is considered spoiled due to the provider not checking, reviewing, and recording refrigerator and freezer temperatures twice daily.
- Vaccine that is considered spoiled due to the provider failing to use currently certified calibrated thermometers (as primary and back-up thermometers) in each VFC storage unit to check temperatures twice daily.
- Vaccine that is spoiled and must be wasted because a provider did not take immediate or appropriate action on out-of-range temperatures to prevent vaccine from becoming spoiled.
- Provider not available to receive a delivery of vaccines during provider's posted hours on file with the order and vaccine was exposed to temperature excursions during return to McKesson.
- Replacement vaccine: health care providers who must re-vaccinate due to negligence in failure to keep vaccine viable (temperatures out of acceptable range) or improper administration will be responsible for replacement of the vaccine needed to re-vaccinate.
- Depending on the outcome of any suspected fraud investigation by Centers for Medicare and Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office and/or the appropriate state Medicaid agency, providers may be required to, among other things, return all VFC vaccine, reimburse the state for the cost of used vaccines, and/or potentially be terminated from the VFC Program. The Department of Public Health reserves any and all rights with respect to any future action.

WASTED VACCINE

- State-provided vaccine given to children or adults who are not eligible to receive it based on the most recent VFC eligibility criteria and Illinois immunization guidelines.
- Discarding vaccine before the manufacturer's expiration date (includes multi-dose vials discarded after 30 days).

LOST VACCINES

- VFC vaccines the provider cannot locate, account for, may have been thrown away, or disposed of against VFC policies.

OTHER

- Failure to call the VFC program within two (2) hours of receiving a VFC delivery when the delivered vaccines do not match the packing list or I-CARE inventory.
- Failure to call the VFC program within two (2) hours to report damaged or compromised VFC vaccine delivery.

- Transferring or transporting VFC vaccines, either refrigerated or frozen vaccines, to another VFC provider without IDPH pre-approval.
- Transferring or transporting varicella-containing vaccines to another VFC provider without IDPH approval on the transportation unit.

SITUATIONS NOT REQUIRING VACCINE REPLACEMENT

Below is a list of situations that are NOT considered "provider negligence." This list is not exhaustive. In these situations, the provider is deemed not to be at fault. You may be required to produce a letter from the alarm/alert company or the power company.

- A commercial carrier or USPS does not deliver to the provider in a timely manner and the provider was available to receive the vaccine during provider's posted hours. Before making the determination that the vaccine is non-viable, first call the vaccine manufacturer.
- A provider who has a contract with an alert/alarm company has a refrigerator that malfunctions, and the alarm/alert company does not notify the provider.
- A provider moves vaccine to a nearby hospital due to anticipated inclement weather, the hospital experiences a power failure, and the Illinois VFC program later deems the vaccine not viable.
- Power was interrupted or discontinued due to a storm, provider is able to confirm that the facility's Vaccine Storage and Emergency Response Plan was followed and after consultation with the vaccine manufacturer(s) and the Illinois VFC program, it is determined that vaccine is not viable.
- A vial that is accidentally dropped or broken by a provider.
- Vaccine that is drawn after physician orders and parental agreement during the visit, but not administered due to parental refusal or a change in physician orders.
- Expired vaccine that is not due to provider negligence (including seasonal influenza vaccine).
- Extraordinary situations not listed above which are deemed by Illinois VFC program to be beyond the provider's control.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Illinois VFC program within 30 days from the date you became aware of the situation.

PROCEDURES FOR RETURNING NONVIABLE VACCINE TO MCKESSON SPECIALTY

- Complete the vaccine incident report to determine if the suspected vaccine is viable or not and fax or email the report, along with the vaccine manufacturer(s) report to the Illinois VFC program. The vaccine incident report is available in I-CARE under "reports."
- Failure to report wasted vaccine to the Illinois VFC program may result in your facility no longer being able to receive state-supplied vaccine.
- No later than six months after the expiration date, return all unopened vials and manufacturer's pre-filled syringes of spoiled or expired vaccine for Excise Tax Credit and disposal to McKesson Specialty, regardless of any financial restitution status applied to the vaccine. Vaccine provided by the Illinois VFC program should never be discarded. Instructions on how to enter expired or wasted vaccines is available in I-CARE.

PROCEDURES FOR VACCINE REPLACEMENT

This updated policy applies to any VFC vaccine documented as wasted.

- The provider will receive a notice from the Illinois VFC program requesting proof of replacement of vaccine reported as wasted to the Illinois VFC Program.
- Acceptable proof is packing list or paid invoice showing type, amount, lot number and expiration date of privately-purchased vaccine that will then be marked and used as VFC vaccine.
- The provider must enter the privately-purchased vaccine in I-CARE and record it as payback to VFC. Guidance will be provided on how to enter the transactions in I-CARE.
- Replacement of the vaccine is due within 30 days of receiving the Illinois VFC program notice.
- The Illinois VFC program will not supply vaccine to the negligent provider until restitution has been made. Enrollment or re-enrollment in the VFC program will not be accepted until full restitution is made.
- If vaccine replacement is required, the VFC provider will be notified by the IDPH VFC program staff.

MODULE 6: ACCOUNTABILITY

VFC VACCINE ORDERS

Providers should order vaccine in accordance with actual vaccine need and avoid stockpiling or build-up of more than a three-month supply. **Providers should maintain enough vaccine inventory to last five weeks, but no more than three months.** Orders may take two to four weeks from submission of order to vaccine delivery.

CDC recommends smaller, more frequent orders rather than large orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit.

All vaccine orders are submitted through I-CARE. Providers must enter the following information to submit an order in I-CARE:

- Patient immunization records showing how each dose of VFC vaccine was administered.
- Temperature logs for all storage units being used to store state-supplied vaccine.
- All temperature excursions must have a Vaccine Incident Report on file.
- Vaccine inventory and accountability for all state supplied vaccine must be up-to-date.
- Clinic must be open at least three days a week with at least four hours a day to be able to receive a delivery.

All Illinois VFC providers must provide individual patient immunization records on how each VFC vaccine was administered. The individual patient immunization records can either be manually entered directly into I-CARE or can be electronically transmitted to I-CARE from the provider's electronic medical record (EMR) system. VFC providers not in compliance will not be able to continue participating in the VFC program.

Providers must also notify the Department when there has been a change in the VFC coordinator or storage units either by calling 217-786-7500 or sending an e-mail to dph.vaccines@illinois.gov.

Providers may also use the “Contact Us” button in I-CARE and select “VFC Illinois” under the category for additional assistance.

PROVIDER PATIENT POPULATION PROFILES

Provider patient population profiles will be used by the VFC administrator and appropriate staff to monitor provider orders. The patient population profile will be automatically populated in I-CARE based on the patient immunization records entered by the clinic in I-CARE or has transmitted from your EMR. The VFC coordinator and appropriate staff must consult the provider profile when reviewing orders to ensure providers are ordering adequate amounts of VFC vaccine for their VFC population. Providers ordering more vaccine than should be needed for their VFC population will be contacted. If orders for excessive amounts of vaccine are placed on a regular basis, the provider will be contacted. The provider may be required to replace wasted vaccines due to excessive ordering. The issue also will be forwarded to the VFC administrator for follow-up at a VFC compliance site visit.

Providers needing to change or correct their patient population profile during the year may send a request to update their profile, with a justification for the change, to the Department by clicking on “Contact Us” in I-CARE and select “VFC Illinois” as the category.

VACCINE RETURN AND WASTE

The vaccine must be documented in I-CARE as waste or expired vaccine. Returns **must be completed within six months after the product expiration or waste date**.

To enter waste and expired/spoiled vaccine in I-CARE:

1. Go to "Vaccines" page in I-CARE.
2. Go to the "Vaccine Lots" tab.
3. Go to the lot number, and click on the "Add Trans" link at the end of that line.
    a. Select Transaction Type of either:
        - "Expired/Spoiled [Return to McKesson]" if you need a return label. Or,
        - "Waste [not to be returned]" if you do not need a return label. (NOT to be used to adjust your inventory levels. Please note below.)
    b. Select the "Waste Code."
    c. Enter the quantity you are wasting.
    d. Type the transaction date.
4. Check the box to confirm the transaction and agree to the warning.
5. Click on "Save" to submit or "Cancel" to not submit the transaction.

NOTE: Attempting to balance your inventory by reporting the doses as waste (not returned to McKesson) is not acceptable nor is this an appropriate way to adjust your inventory instead of reporting patient vaccinations on doses administered. All reports of wasted vaccines will be transmitted directly to CDC. VFC providers may be required to replace any excessive amounts of wasted vaccines or frequent reports of wasted vaccines with privately-purchased vaccines.

These transactions are transmitted directly to the Centers for Disease Control (CDC) to report provider's inventory that is wasted (not returned to McKesson) and expired/spoiled (returned to McKesson). Providers reporting expired/spoiled vaccines will receive an e-mail when the report has been received by CDC and should expect a return label within seven (7) days of the e-mail date. All expired VFC vaccines must be returned to McKesson for excise tax credit.

The following vaccines should never be returned to McKesson:

- Used syringes, with or without needles;
- Broken vials;
- Wasted products such as a syringe that was drawn up but not used;
- Any multi-dose vial from which some doses have been withdrawn;
- IG, HBIG, PPD;
- Diluent (expired or not expired); or
- Private-purchased vaccines.

The items listed above should be disposed of according to usual medical biosafety procedures, and according to your immunization program's procedures.

The following items must be returned to McKesson:

- Spoiled or expired product in its original vial or manufacturer prefilled syringe.
- Unused manufacturer prefilled syringes with an NDC printed on them.

Federal excise tax (FET) credits can only be processed for unopened vials and for unopened manufacturer prefilled syringes. Returns of product other than these are not eligible for FET credit.

VFC AND MULTI-DOSE VIALS

Opened vials of multi-dose vaccines should not be wasted before the manufacturer's expiration date. The Vaccine Loss and Replacement Policy specifies, "Discarding vaccine before the manufacturer's expiration date (includes multi-dose vials discarded after 30 days)" as an item that requires replacement by VFC providers. VFC providers should ensure their organization's policy and procedures regarding opened multi-dose vaccine vials are in compliance with VFC policies.

The Joint Commission website has specifically addressed the issue of discarding open multi-dose vaccines (available at http://www.jointcommission.org/mobile/standards_information/jcfaqdetails.aspx?StandardsFAQId=143&StandardsFAQChapterId=76):

Q. Do vaccines need to follow the 28-day rule?

A. Currently, vaccines are exempted from this requirement. The CDC Immunization Program states that vaccines are to be discarded per the manufacturer's expiration date. The Joint Commission is applying this approach to all vaccines (whether a part of the CDC or state immunization program or purchased by healthcare facilities) with the understanding that the vaccines are stored and handled appropriately (correct temperature is maintained, frequency of temperature checks, etc.). Following the guidelines provided in the package insert is very important to assure integrity of the vaccine.

According to the General Recommendations on Immunization of the Advisory Committee on Immunization Practices, published January 28, 2011, page 19, "For multi-dose vials that do not require reconstitution, doses that remain after withdrawal of a dose can be administered until the expiration date printed on the vial or vaccine packaging if the vial has been stored correctly and the vaccine is not visibly contaminated, unless otherwise specified by the manufacturer." CDC MMWR Vol 60 No 2 January 28, 2011 and available at http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf.

Following is a letter from Sanofi Pasteur confirming that multi-dose vials that have been opened and stored under proper conditions may continue to be used through the products documented expiration date on the vial or on the product box.

SANOFI PASTEUR

Dear Healthcare Provider:

This letter is in response to your inquiry regarding multidose vials of IPOL® (Poliovirus Vaccine Inactivated), Typhim® (Typhoid Vi Polysaccharide Vaccine) or Fluzone® (Influenza Virus Vaccine). Sanofi Pasteur Inc. supports the use of our multidose vials of vaccine until the expiration date stamped on the vial provided the product is maintained at the required storage temperature of 2°- 8°C (35°- 46°F) and is properly handled. This includes vials that have had doses withdrawn from them. However, we advise that multidose vials that have been entered and have not been maintained at 2°- 8°C (35°- 46°F) should be discarded after 30 minutes (total) exposure to room temperature.

Tubersol®, Tuberculin Purified Protein Derivative (Mantoux) vials must be discarded 30 days after opening as stated in the Package Insert. (1)

The Centers for Disease Control and Prevention (CDC) also supports the use of multidose vials that have had doses withdrawn from them until expiration as referenced below:

Storage and Handling of Immunobiologics-Multidose Vials
Certain vaccines (i.e., quadrivalent meningococcal polysaccharide vaccine [MPSV4], PPSV, TIV, IPV, and yellow fever) are available in multidose vials. Because several doses are withdrawn from the same vial, proper technique must be followed to prevent contamination. For multidose vials that do not require reconstitution, doses that remain after withdrawal of a dose can be administered until the expiration date printed on the vial or vaccine packaging if the vial has been stored correctly and the vaccine is not visibly contaminated, unless otherwise specified by the manufacturer. Multidose vials that require reconstitution must be used within the interval specified by the manufacturer. After reconstitution, the new expiration date should be written on the vial. (2)

(1) Package inserts are available at www.vaccineshoppe.com.

(2) MMWR: General Recommendations on Immunization - January 28, 2011 / 60(RR02) available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm?s_cid=rr6002a1_w.

Sanofi Pasteur Inc. provides this information as a service for your personal use. We hope this information is of use to you. If you have any further questions please do not hesitate to contact me at 1-800-822-2463.

Sincerely,

Karen Miskinis

Karen Miskinis RN
Deputy Director
Medical Information Services US
Sanofi Pasteur

Discovery Drive, Swiftwater, Pennsylvania 18370 - Tel.: 800-822-2463 - www.sanofipasteur.us
SANOFI PASTEUR Inc.

PROVIDER-TO-PROVIDER TRANSFER OF VACCINES

The VFC program discourages regular transport of vaccines.

- Proper management of vaccine inventory plays a major role in preventing the need to transport vaccines.
- IDPH must review and approve all requests to transfer vaccines BEFORE the transfer occurs.
- Given that providers generally receive vaccine within a week of approval, more frequent orders are preferred over large orders that may increase the risk of expiry in the provider's office.

If transport must occur, the VFC program strongly recommends the use of a thermometer with continuous monitoring and recording capabilities.

- All thermometers should have a current and valid certificate of calibration.
- The VFC program does not recommend, or find as an acceptable alternative, one-time use temperature indicators since they do not provide adequate data on excursions that may occur during transport.

TRANSPORT OR SHIPPING

The terms "transport" and "shipping" have different meanings although often used interchangeably.

- Transport involves the movement of vaccine over a short time and distance between providers.
- Transport is typically performed by providers using private vehicles or courier services.
- The expected length of transport is less than eight (8) hours or regular business day.
- The VFC program's expectation is that transporting vaccines should be an extremely rare occurrence.
- Shipping, as compared to transport, typically involves further distance and time to move vaccine between locations.
- Often, vaccine is moved using a large, shipping management service and requires adherence to shipping standards that go beyond CDC guidance for the transport of vaccine.
- The VFC program does not allow providers to ship vaccines due to the potential risks to the cold chain and ultimately the viability of the vaccine.

PROCEDURE

Providers who have excess vaccine on hand that will not be used in three to six months before expiration are encouraged to transfer this vaccine to other Illinois VFC providers to utilize, and thus avoid being charged for wasted vaccine. Providers should begin this process within three to six months of the vaccine expiring. **It is the provider's responsibility to find another provider willing to accept the vaccine, and also to properly pack and ship the vaccine to that provider following standard cold-chain procedures.** Providers must allow up to 10 business days for transfer approval requests to be reviewed.

Transfers should only occur for the following reasons:

- Vaccine is six months or less from outdate, and unable to be used by provider.
- Area outbreak resulting in unexpected surge of walk-in patients.
- Clinic closure requiring redistributing vaccines to other VFC providers.
- Seasonal clinic needing to transfer vaccine to other VFC providers at end of time facility will be open. (i.e. School Health Clinic or Racing Industry)

Providers may not transfer influenza vaccine. Varicella-containing vaccines (MMRV, VAR) may only be transported in a portable freezer. IDPH will review requests to transport varicella-containing vaccines on a case-by-case basis to ensure transportation guidelines are followed.

If a provider needs a vaccine, they may order the vaccine as vaccine orders are usually shipped sooner than the 10 business days it could take to approve a transfer of vaccines. Transfers should be done on a rare basis and only for the reasons stated above. Vaccines should remain with the original location it was delivered to if at all possible, to avoid a possible break in the cold chain rendering the vaccine non-viable.

Providers must obtain pre-approval from IDPH before any transfers. The transfer pre-approval request form, with transportation guidelines, is available in I-CARE and at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/vfc-program.

PROVIDER MOVING TO A NEW LOCATION

VFC providers planning to move their clinic to a new location must notify the immunization program before the clinic moves so the equipment and plan to transport the VFC vaccines may be reviewed and approved. Contact the immunization program at DPH.Vaccines@illinois.gov or by telephone at 217-786-7500.

Moving or installing a new refrigerator and freezer will take time to stabilize the temperatures within the unit. It may take two to seven days to stabilize the temperature between 35 F and 46 F (2 C and 8 C) in a newly installed or repaired refrigerator. Likewise, it may take two to three days to stabilize the temperature between -58°F and +5°F (-50°C and -15°C) in a newly installed or repaired freezer. VFC providers must allow a week of refrigerator and freezer temperature readings/recordings a minimum of two times each workday, including minimum/maximum temperatures one time each morning to make sure temperatures are within appropriate ranges before using units to store vaccines. (Source: *CDC Storage and Handling Toolkit*).

VFC PROVIDER WITHDRAWAL

Unfortunately, some circumstances may occur that necessitate VFC providers withdrawing from their role as an approved provider. The cause for these circumstances may vary, but timely and appropriate notification by the provider is desired and expected. The following steps should occur:

- The clinic should complete the VFC Provider Withdraw Form available in I-CARE or at http://www.dph.illinois.gov/topics-services/prevention-wellness/immunization/vfc-program and fax or e-mail to the Illinois VFC program. Be sure to include your handwritten temperature logs for the previous three months and your current VFC inventory.
- If the enrollment agreement is terminated, the provider agrees to properly return any unused VFC vaccine within 30 days of the termination date. The provider may not continue to administer VFC vaccines after the termination date.
- If the clinic is able to provide documentation of the cold chain being maintained, the clinic must find another VFC provider to transfer their remaining vaccines. The Department will review documentation of the cold chain and advise the provider of next steps.
- The Department will contact the provider to follow up on the withdraw notification.

MODULE 7: VFC SITE VISITS

To ensure the quality of VFC vaccine and the integrity of the VFC program, the Department conducts the following type of provider site visits.

- Enrollment site visits (discussed in Module 3, page 16)
- Compliance site visits
- Unannounced storage and handling site visits

VFC visits help determine compliance with VFC program requirements. This includes identifying potential issues with VFC vaccine accountability and determining whether VFC vaccines are being handled, stored, and administered in accordance with the laws and policies governing the VFC program.

The review and evaluation of VFC provider practices involves assessing verbal, written, and visual evidence encountered during the visit to determine if provider sites are following the requirements of the VFC program.

The goals of these visits are to:

- Identify areas where providers are doing well and areas needing additional follow-up
- Identify the educational needs of VFC providers in order to support them with meeting program requirements
- Ensure that VFC-eligible children receive properly managed and viable vaccine

Additionally, site visits are critical opportunities to engage provider staff and develop and strengthen ongoing relationships.

VFC COMPLIANCE VISIT

All enrolled and active VFC providers must receive a VFC compliance site visit every other year, at minimum, to ensure compliance with VFC program standards.

- Enrolled and active providers are providers that are enrolled in the VFC Program and have ordered vaccine within the past 12 months.
- Conducting a VFC compliance site visit with providers every other year is a minimum-level requirement. Providers may receive a VFC compliance site visit on a more frequent basis.
- A new provider must be enrolled and active in the VFC program at least three to six months before receiving a VFC compliance site visit.

The VFC compliance visit requires availability of key staff that can accurately provide a realistic picture of how the clinic is implementing the VFC program on a daily basis. The VFC compliance site visit includes staff guidance and education on “best practices” to store and manage VFC vaccines, ensure all VFC-eligible children are receiving properly maintained vaccines, and address practice-based questions about VFC program initiatives.

STORAGE AND HANDLING SITE VISIT

The vaccine storage and handling visit serves as a “spot check” for proper practices on storage and handling of VFC vaccine. The goal of these visits is to provide guidance and education, to protect the vaccine, and to ensure VFC-eligible children are receiving properly managed vaccines.

VFC providers may be prioritized for an unannounced storage and handling visit based on the following:

- The provider's previous history with storage and handling compliance issues
- Time since the last site visit
- A newly enrolled provider

The current vaccine storage and handling toolkit was updated in May 2014 and is available at http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf. The toolkit outlines best practice strategies and recommendations on the following:

- Vaccine cold chain
- Storage and handling plans
- Staff
- Vaccine storage equipment
- Temperature monitoring equipment
- Vaccine storage and handling best practices
- Storage unit temperature monitoring
- Troubleshooting
- Vaccine inventory management
- Vaccine deliveries
- Vaccine transport
- Vaccine preparation
- Vaccine disposal

Please be advised that checks to monitor vaccine storage unit temperatures by pharmaceutical representatives or other entities do not satisfy the CDC mandate for storage and handling visit requirements.

CONDUCTING THE SITE VISIT

The VFC site visits are conducted either by the Department's immunization staff or by local health departments trained by the Department to act as delegates to perform compliance visits.

FOLLOWING UP AFTER THE SITE VISIT

During or at the end of the VFC compliance site visit, VFC staff shall provide education to the provider staff when non-compliant behaviors or practices are observed or encountered in order to correct the situations. If the provider is found to be non-compliant, a provider follow-up plan will be completed and reviewed with the provider office.

MODULE 8: FRAUD AND ABUSE

OVERVIEW

As childhood vaccines become more expensive and immunization programs more complex, the VFC program becomes vulnerable to fraud and abuse. A working understanding of what constitutes fraud and abuse is critical for all persons working in the VFC program. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of this guide, the following definitions will be used:

Fraud: An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse: Provider practices inconsistent with sound fiscal, business or medical practices and result in an unnecessary cost to the Medicaid program (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company or patient); or in reimbursement for services not medically necessary or fail to meet professionally recognized standards for health care. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

The following are additional definitions used in the VFC program.

Oversight: Illinois specifies any suspected case of fraud and abuse should immediately be reported to the Department's VFC administrator, immunization assistant section chief, or immunization section chief. Within five working days, the Department's Immunization Program will contact the provider in question or the person reporting the suspected fraud and abuse to perform an in-depth interview, with documentation recorded on the Department's fraud and abuse form. A file will be established for each provider suspected of fraud and abuse with a copy of all verbal and written correspondence maintained, as well as maintaining a fraud and abuse referral database. The Department's Immunization Program will follow-up with the external agency within ten working days, or sooner.

Enforcement: If the VFC program determines from the assessment of information available that the situation requires referral for further investigation by an outside agency, the VFC program will make these referrals within ten working days from assessment. All suspected cases of fraud and abuse that require further investigation must be referred first to the immunization section chief or equivalent for referral to the Medicaid Integrity Group (MIG) and the CDC, with notification of the referral also sent to Department's legal counsel and auditor.

Termination: The Department's Immunization Program has the right to exclude or terminate providers from the VFC program that are not following any Illinois VFC program or I-CARE requirements. Vaccine will be removed from the provider's possession and the provider will be prohibited from receiving future shipments until the exclusion is lifted. The terminated provider or entity may be eligible to re-apply for the VFC and I-CARE Programs after the exclusion is lifted. The Illinois VFC program will terminate providers from participating in the VFC program if the provider is found to be in non-payment status under Medicare, Medicaid, and other federal health care programs. Termination of providers may also occur due to Office of Inspector General (OIG) sanction, failure to renew license or certification registration, revocation of professional license or certification, or termination by the Illinois Medicaid Agency. Providers that are terminated from the VFC program (both voluntarily and involuntarily) will be removed from active status in the VFC program, removed from VFC Health Alert Notification (HAN) lists, and excluded on reports to the Illinois Medicaid agency requesting data on active VFC providers.

All cases of suspected fraud and abuse will be handled according to this policy and the CDC Non-Compliance with VFC Requirements Protocol.

FRAUD AND ABUSE POLICY

The Fraud and Abuse Policy is a comprehensive written policy that addresses prevention, detection, investigation, and resolution of fraud and abuse allegations. VFC staff must be familiar with this policy and be able to prevent, to identify and to follow-up on situations that involve suspected fraud or abuse of the VFC program.

When providers enroll in the VFC program, they agree to comply with all the requirements of the program. Lack of adherence to the VFC program requirements by an enrolled provider could lead to fraud and abuse of the VFC program by that provider.

Failure to comply with VFC requirements is defined as:

- Any VFC-enrolled provider who is identified as not maintaining any of the federal requirements for the VFC program as defined in the enrollment agreement.

Failure to comply may be identified by:

- VFC program staff
- The enrolled provider's staff, or
- A third party

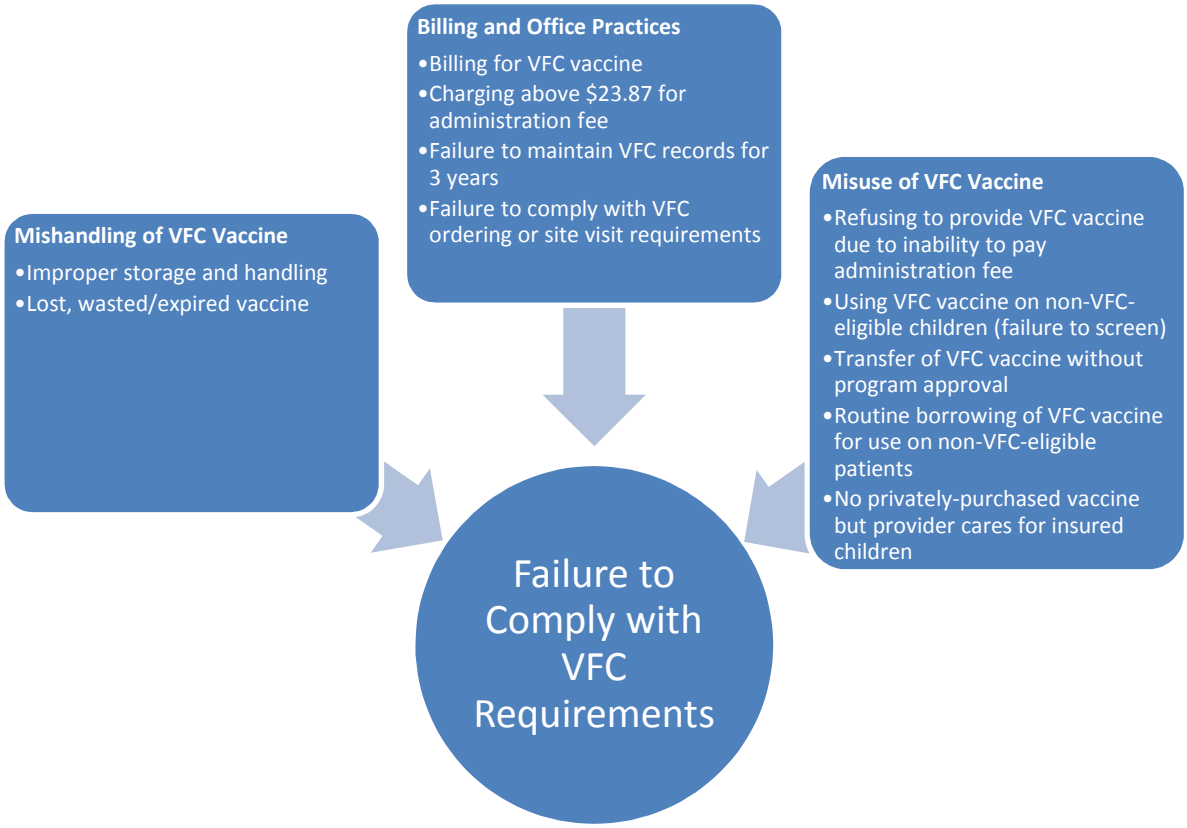
Non-compliance with program requirements may occur due to an unintentional lack of understanding of the VFC program requirements, or the behavior may be intentional. **If the non-compliance appears intentional and the provider has received financial benefits from the behavior, the situation would require immediate referral to an outside agency for investigation of suspected VFC fraud and abuse.**

EXAMPLES OF FRAUD AND ABUSE

Fraud or abuse can occur in many ways, and some types of fraud and abuse are easier for the VFC program to prevent or detect than others, depending on how the VFC program is implemented. The VFC program will use provider profiles, ordering patterns, VFC site visits, temperature logs and doses administered reports to monitor provider compliance with VFC program requirements. Some examples of potential fraud are:

- Providing VFC vaccine to non-VFC-eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC-funded vaccine
- Charging more than the established maximum regional charge ($23.87) for administration of a VFC funded vaccine to a federally vaccine-eligible child
- Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay for the administration fee
- Failing to implement provider enrollment requirements of the VFC program
- Failing to screen for and document eligibility status at every visit
- Failing to maintain VFC records and comply with other requirements of the VFC program
- Failing to fully account for VFC-funded vaccine
- Failing to properly store and handle VFC vaccine

- Ordering VFC vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering VFC doses of vaccine
- Waste of VFC vaccine



ALLEGATIONS OF SUSPECTED FRAUD AND ABUSE

The Department will investigate all allegations of suspected fraud and abuse and will determine if the situation is intentional fraud and abuse or unintentional abuse or error due to an excusable lack of knowledge of the VFC program with no purposeful intent to misrepresent or defraud the VFC program. If the situation is found to be unintentional, an educational intervention will be made, and arrangements will be established to replace any vaccine used inappropriately.

The Department's Immunization Program staff will provide in-depth education to the provider's key staff about the VFC program and Illinois VFC enrollment and accountability requirements. The provider will be required to complete and return an acknowledgement of receipt of the follow-up plan detailing the steps that will be taken to prevent further incidents. This signed plan must be returned within one month. The provider will be advised that any recurrence of suspected fraud and abuse may result in termination from the VFC program and referral to an external agency for investigation.

If the investigation determines the situation is intentional, the situation will be reported to an external agency for investigation. All suspected cases of fraud and abuse that require further investigation will first be referred to the immunization section chief or equivalent for review by the Office of Health Protection and the Department's legal

counsel and auditor. Suspected cases of fraud and abuse will then be referred to the Medicaid Integrity Group (MIG) and the CDC.

Suspected cases of fraud and abuse will be referred to the Centers for Medicare and Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office for further investigation. CMS/MIG may refer the suspected case to the appropriate state Medicaid agency for further investigation. VFC ordering privileges may be suspended when a referral is made to CMS/MIG. Depending on the outcome of any investigation by CMS/MIG and/or the appropriate state Medicaid agency, providers may be required to, among other things, return all VFC vaccine, reimburse the state for the cost of used vaccines, and/or potentially be terminated from the VFC Program. The Department reserves any and all rights with respect to any future action.

FRAUD AND ABUSE CONTACTS

Suspected VFC fraud or abuse may be reported to any of the following Department staff.

Linda Kasebier, VFC administrator, is designated as the primary contact.

Linda.Kasebier@illinois.gov

Carol Finley, assistant chief, Immunization Section, is designated as first back-up.

Carol.Finley@illinois.gov

William Moran, chief, Immunization Section, is designated as second back-up.

William.Moran@illinois.gov

Each of these individuals may be contacted at:

525 W. Jefferson Street, 1st Floor
Springfield, IL 62761
217-785-1455 or 800-526-4372

ONGOING PROVIDER MONITORING PROCEDURES

The Illinois VFC program will exclude providers from participating in the VFC program if the provider is found to be in non-payment status under Medicare, Medicaid, and other Federal health care programs. Exclusion of providers also may occur due to Office of Inspector General (OIG) sanction, failure to renew license or certification registration, revocation of professional license or certification, or termination by the state Medicaid agency. The Illinois Immunization Program will monitor OIG exclusions by checking the List of Excluded Individuals and Entities on the OIG website upon provider enrollment at oig.hhs.gov/fraud/exclusions.asp. This list will be checked monthly thereafter and compared to currently enrolled providers. Claims are not processed by Medicaid for providers on the OIG list. **Providers are strongly encouraged to check the OIG website list of excluded individuals/entities prior to hiring or contracting with any individuals or entities. Enrolled providers who employ a person (including, but not limited to, physicians, mid-level practitioners, nurses or nursing aides) from the excluded provider list will be terminated from the program and the state Medicaid and MIG agencies will be notified.**

The Department's Immunization Program also has the right to exclude providers not following any other Illinois VFC program or I-CARE requirements. Vaccine will be removed from the provider's possession and the provider

will be prohibited from receiving future shipments until the exclusion is lifted. The excluded provider or entity will be required to re-apply for the VFC and I-CARE Programs after the exclusion is lifted. The Illinois Immunization Program may share information with the state attorney's office, and the Medicaid Fraud and Abuse Unit regarding allegations and exclusions due to fraud and abuse.

REPORTING VFC PROVIDER TERMINATIONS

Providers terminated from the VFC program (both voluntarily and involuntarily) will be removed from active status in the VFC program, removed from VFC Health Alert Notification (HAN) lists and excluded on reports to the state Medicaid agency requesting data on active VFC providers.

APPENDICES

The following documents are located in the appendix.

- VFC Tip Sheet – Certified Calibrated Thermometers
- VFC Tip Sheet – Manual Defrost Storage Units
- VFC Tip Sheet – Products with Multiple NDCs
- VFC Tip Sheet – Vaccine Storage Unit Checklist
- Glossary of Important VFC Terms

VFC TIP SHEET – CERTIFIED CALIBRATED THERMOMETERS

The recommended method to ensure that a refrigerator or freezer is maintaining the proper temperature for vaccine storage is to check and record the temperature manually at least twice a day each workday, and no fewer than three times a week. VFC providers must adhere to the following guidance:

- **Each refrigerator and freezer must have a calibrated working thermometer certified in accordance with the National Institute of Standards and Technology (NIST)** or a laboratory recognized by NIST, placed in a central area inside each compartment used for storing vaccine.
- As of January 1, 2015, providers are required to have at least one back up thermometer with a current certificate of calibration on hand (not stored in unit alongside current thermometer). It should be available in case a thermometer in use is no longer working appropriately or calibration testing of the current equipment is required.
- Calibration testing of thermometers must be performed at least every two years from the last calibration testing date (date certificate issued).
- Handwritten temperature logs and I-CARE temperature logs must have the time of the reading and initials of the provider staff recording the temperatures.
- Record temperatures in I-CARE at minimum weekly.
- Record thermometer calibration information in I-CARE, including the date calibration certification is due.

Providers must have a certified calibrated thermometer in each unit storing VFC vaccines. CDC recommends use of a **digital data logger thermometer** with a detachable probe in a buffered material (e.g., glycol) with continuous monitoring capabilities. The temperature should be easily readable from the outside of the unit. Additional recommended features include:

- A detachable probe in a buffered material;
- Provides current, minimum and maximum temperatures that are easily readable from the outside of the unit
- Alarm that notifies the provider of out-of-range temperatures
- Viewable low battery indicator
- Capability of +/- 1°F (0.5°C) accuracy
- Provides memory storage of at least 4,000 readings;
- Provides capability to not write over old data – stops recording when memory is full; and
- Equipped with user programmable logging interval (or reading rate)

CDC **strongly** recommends that clinics that are routinely closed for more than two consecutive days, and do not have staff that assess and record temperatures twice a day on days when the office is closed, use a continuously monitoring and recording digital data logger with downloadable capabilities meeting the digital data logger characteristics listed above.

Providers are responsible for maintaining current Certificates of Traceability and Calibration Testing.[2] Calibration testing of all thermometers must be performed at least every two years from the last calibration testing date (date certificate issued). Provider must keep the certificate of calibration for each thermometer and back-up thermometer, and make them available for inspection during site visits.

[2] Certificate of Traceability and Calibration Testing (also known as Report of Calibration) is a certificate that informs the user of a thermometer's level of accuracy compared to a recognized standard based on testing by the National Institute of Standards and Technology (NIST).

As of April 2013, CDC will allow calibration testing and traceability to be performed by a laboratory accredited by an ILAC MRA signatory body **OR as an alternative** by a laboratory or manufacturer that provides documentation that demonstrates that calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability. **Between the two options, CDC recommends that testing be performed by ILAC accredited laboratories.** An ILAC MRA accredited laboratory is the easiest way to identify that the instrument has been tested correctly according to international standards.

CHECKLIST FOR CERTIFICATE OF CALIBRATION REPORTS

A. If calibration testing performed was by an ILAC accredited laboratory

- ILAC accredited laboratories are:

Tip: Look on the certificate for the laboratory name or logo

ILAC/MRA Signatory body accredited Laboratory

The Following Table lists the accredited laboratories

A2LA	L-A-B	ACLASS	IAS	PJLA	NVLAP
	LABORATORY ACCREDITATION BUREAU				

- The certificate of calibration must have these items:

  - ☐ Name of device (optional)
  - ☐ Model number
  - ☐ Serial number
  - ☐ Date of calibration (report or issue date)
  - ☐ Measurement results indicate unit passed testing: This may be listed under "Pass/Fail," "In Tolerance," or "In Tol."
  - ☐ The documented uncertainty is listed within suitable limits (recommended uncertainty = +/- 1F or 0.5 C): This may be listed under "Uncertainty," "±U," or "+/-."

B. If certificate does not identify an accredited laboratory

- These manufacturers or laboratories must provide a Certificate of Traceability or Report of Calibration Test that must include the following elements:

  - ☐ Name of device (optional)
  - ☐ Model number
  - ☐ Serial number
  - ☐ Date of calibration (report or issue date)
  - ☐ Measurement results indicate unit passed testing: This may be listed under "Pass/Fail," "In Tolerance," or "In Tol."
  - ☐ The documented uncertainty is listed within suitable limits (recommended uncertainty = +/- 1F or 0.5 C): This may be listed under "Uncertainty," "±U," or "+/-."
  - ☐ Statement that calibration testing conforms to ISO 17025

CERTIFICATE OF CALIBRATION – SAMPLE 1

Certificate Of Calibration

Digital Thermometer W Thermistor Probe

Report No. 0926

Calibration Laboratory 23

Customer: TAGE HOSPITAL
185 GRAFT RD
TOWNS, VA 00216

Make: TROL COP
Model: 41CC with P10PROBE
Serial # 8042
/Range: -200 TO 800 °C IN 0.01 °C DIVISIONS
Accuracy/Tolerance : +/- 0.1 % + 0.2 °C BELOW 200 °C
Item Received : IN TOLERANCE
Calibration Location: SCH Temperature Laboratory

Date Received: 09/26/2012
Calibration Date: 09/26/2012
Customer Specified Due Date: 09/2013
PO# : 011513
Contact: JAY BELCHER
Temperature: 21.6 TO 21.8 °C / RH% 47 TO 47
CONDITION RECEIVED : IN SPEC
Item Returned: IN TOLERANCE
Equipment Location: LAB

Notes : CALIBRATED AT CUSTOMERS SPECIFIED POINTS OF USE ONLY !

Nominal	Actual (STD)	Measured (UUT)	Deviation (UUT)	Units	Tolerance (±)	Uncertainty (+)	Pass/Fail
0	0.028	0.08	0.05	°C	0.20		PASS
20	20.017	20.15	0.13	°C	0.22		PASS
35	35.003	35.20	0.20	°C	0.24		PASS

Deviation rounded to the readability of UUT

The measurement traceability and calibration process used for conformance verification of the above instrument meets the requirements of ISO 17025:2005. The reported uncertainties reflect those of type B (Systematic errors associated with the standards and the [illegible]), and type A (Random errors of the process) the type A and type B uncertainties are combined in accordance with [illegible] Note 1297 using the RSS method and are reported at the coverage factor k= [illegible] confidence level of 95%. The date code as it appears on this report does not imply that the instrument will maintain [illegible] accuracy for any given length of time unless supported with further documentation (e.g. statistical etc.) which affirms such [illegible] the responsibility of the end user. Many factors may contribute to instrument in-accuracy over time such as drift, environment, transportation, frequency of use etc. The reported results reflect readings obtained at the time of test only. The reported uncertainty is [illegible] those associated with the calibration process itself and not the instrument under test. Where UUT is a digital electronic instrument add 0.6 of the least significant digit to the above stated uncertainty. The instrument is considered to be in tolerance based on observed results (Deviation or departure from nominal value) falling anywhere within its specified tolerance without consideration of applied uncertainty. this document shall not be reproduced except in full without the written approval [illegible].
Procedure Used QCS 3015 (QCSD) (QCSTD 030106-3)

TRACEABLE STANDARDS USED:

Fluke 1522	S/N: A6C2[illegible]	Cal Due : 10/2012	
ERTCO-EUTECH	S/N: 304[illegible]	Cal Due : 01/2013	X
HART SCI[illegible]	S/N: [illegible]	Cal Due : 04/2013	X

Certified By: Howard Ri[illegible] Date: 09/26/2012

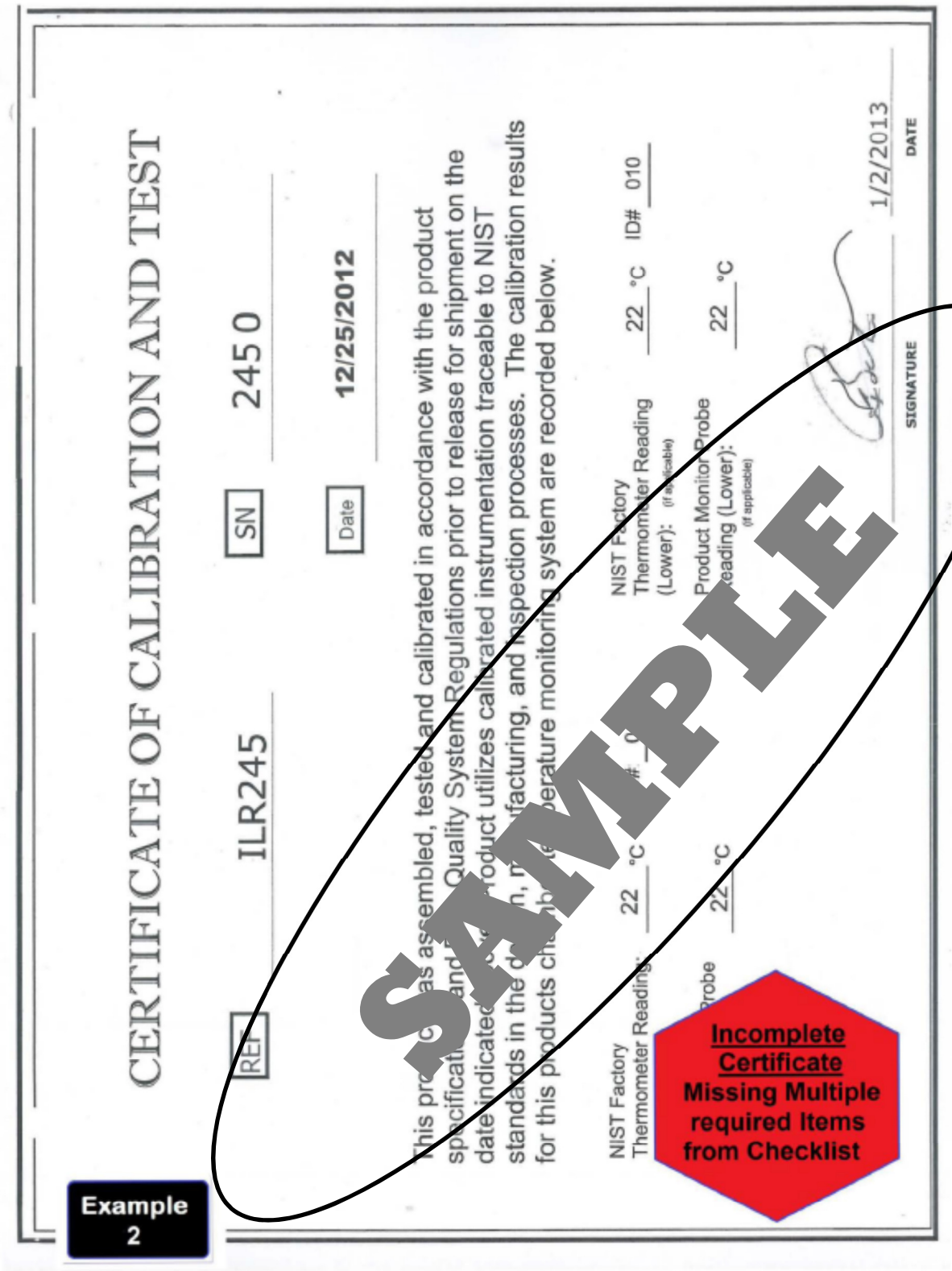
Approved By: [illegible] Title: Metrologist Date: 09/26/[illegible]

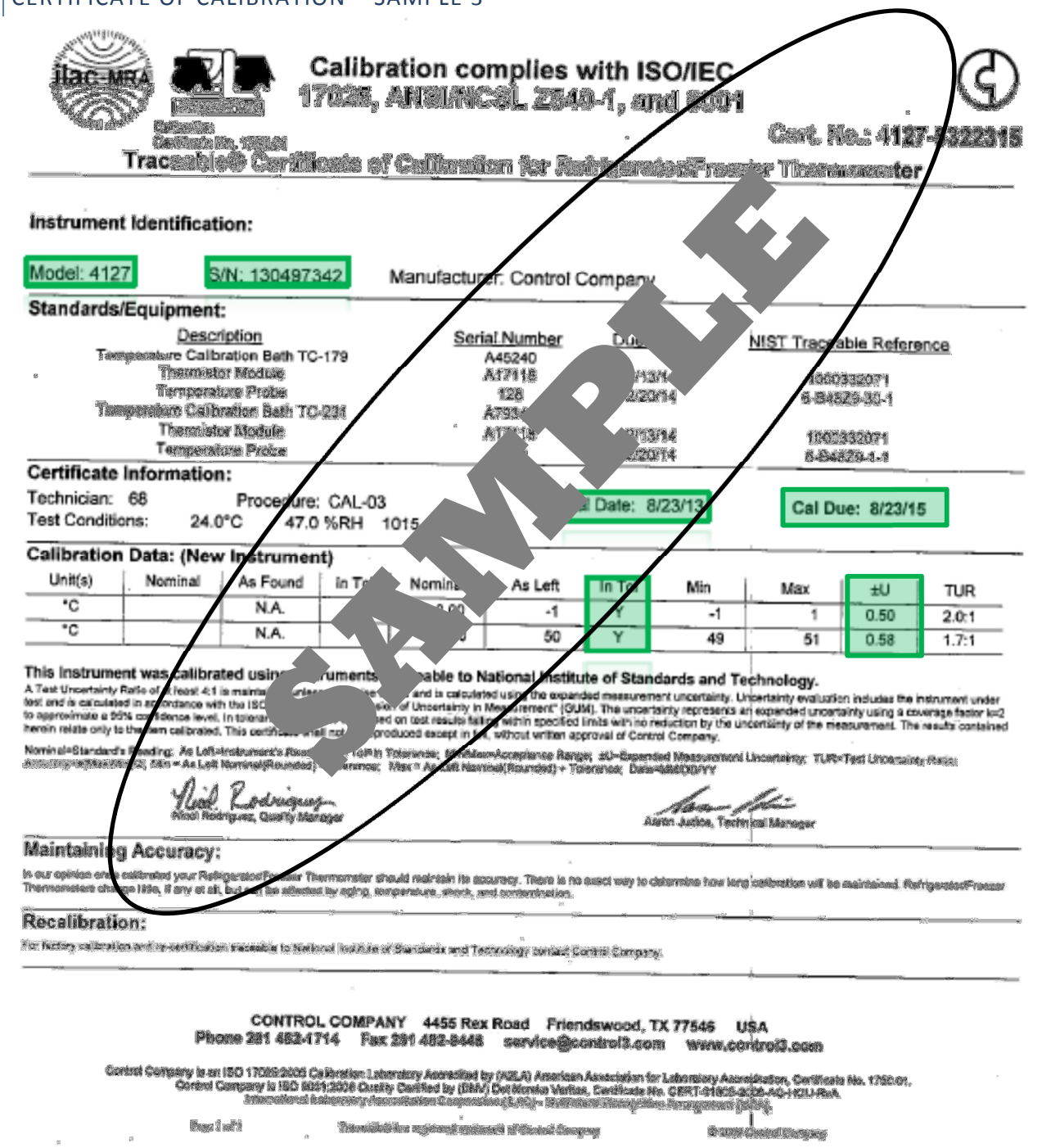
SAMPLE

Example 1

Good Certificate

Meets all items under "A" from the Checklist


CERTIFICATE OF CALIBRATION AND TEST
REF
ILR245
SN
245 0
Date
12/25/2012
This pr as assembled, tested and calibrated in accordance with the product
specificati and Quality System Regulations prior to release for shipment on the
date indicated oduct utilizes calibrated instrumentation traceable to NIST
standards in the facturing, and inspection processes. The calibration results
for this products ch erature monitoring system are recorded below.
NIST Factory
Thermometer Reading:
22 °C
NIST Factory
Thermometer Reading
(Lower):
22 °C
ID# 010
Probe
22 °C
Product Monitor Probe
Reading (Lower):
22 °C
1/2/2013
SIGNATURE
DATE
SAMPLE
Example 2
Incomplete Certificate
Missing Multiple required Items from Checklist



Calibration complies with ISO/IEC 17025, ANSI/NCSL Z540-1, and Q1001

Cert. No.: 4127-[illegible]15

Traceable® Certificate of Calibration for Refrigerator/Freezer Thermometer

Instrument Identification:

Model: 4127 S/N: 130497342 Manufacturer: Control Company

Standards/Equipment:

Description	Serial Number	Due	NIST Traceable Reference
Temperature Calibration Bath TC-179	A45240		
Thermistor Module	A17118	[illegible]/13/14	100033207[illegible]
Temperature Probe	128	[illegible]/23/14	5-[illegible]-1
Temperature Calibration Bath TC-231	A793[illegible]		
Thermistor Module	A1[illegible]	[illegible]/13/14	100033207[illegible]
Temperature Probe	[illegible]	[illegible]/20/14	5-[illegible]-1

Certificate Information:

Technician: 68 Procedure: CAL-03

Test Conditions: 24.0°C 47.0 %RH 1015

[illegible] Date: 8/23/13 Cal Due: 8/23/15

Calibration Data: (New Instrument)

Unit(s)	Nominal	As Found	In Tol	Nominal	As Left	In Tol	Min	Max	±U	TUR
°C		N.A.		[illegible]	-1	Y	-1	1	0.50	2.0:1
°C		N.A.		[illegible]	50	Y	49	51	0.58	1.7:1

This instrument was calibrated using [illegible]ruments traceable to National Institute of Standards and Technology.

A Test Uncertainty Ratio of at least 4:1 is maintained [illegible] and is calculated using the expanded measurement uncertainty. Uncertainty evaluation includes the instrument under test and is calculated in accordance with the ISO [illegible]ssion of Uncertainty in Measurement" (GUM). The uncertainty represents an expanded uncertainty using a coverage factor k=2 to approximate a 95% confidence level. In tolerance [illegible]ed on test results falling within specified limits with no reduction by the uncertainty of the measurement. The results contained herein relate only to the item calibrated. This certificate shall not be reproduced except in full, without written approval of Control Company.

Nominal=Standard's Reading; As Left/As Found=Instrument's Reading; In Tol=In Tolerance; Min=Minimum Acceptance Range; ±U=Expanded Measurement Uncertainty; TUR=Test Uncertainty Ratio; [illegible]; TAR = As Left Nominal(Rounded) [illegible]rance; Max = As Left Nominal(Rounded) + Tolerance; Date=MM/DD/YY

Nicol Rodriguez, Quality Manager

Aaron Justice, Technical Manager

Maintaining Accuracy:

In our opinion and calibrated your Refrigerator/Freezer Thermometer should maintain its accuracy. There is no exact way to determine how long calibration will be maintained. Refrigerator/Freezer Thermometers change little, if any at all, but can be affected by aging, temperature, shock, and contamination.

Recalibration:

For factory calibration and re-certification traceable to National Institute of Standards and Technology, contact Control Company.

CONTROL COMPANY 4455 Rex Road Friendswood, TX 77546 USA
Phone 281 482-1714 Fax 281 482-9448 service@control3.com www.control3.com

Control Company is an ISO 17025:2005 Calibration Laboratory Accredited by (A2LA) American Association for Laboratory Accreditation, Certificate No. 1760.01.
Control Company is ISO 9001:2008 Quality Certified by (DNV) Det Norske Veritas, Certificate No. CERT-01605-2006-AQ-HOU-RvA.
[illegible]

Page 1 of 1 [illegible] registered trademark of Control Company [illegible]

SAMPLE

Good Certificate
Meets all items under "A" from the Checklist.

Example

VFC TIP SHEET – MANUAL DEFROST STORAGE UNITS

The Centers for Disease Control and Prevention (CDC) currently recommends stand-alone refrigerators and stand-alone freezers for vaccine storage. The CDC recommends auto defrost (self-defrosting) units, but if a provider has a unit with a manual defrost, he/she should have another storage unit for temporary storage capable of maintaining correct temperatures to place the vaccine in while defrosting the main unit.

The following is a suggested procedure for defrosting a manual defrost unit:

It is normal for ice and frost to accumulate inside the freezer and the refrigerator compartment depending on the type of storage unit. A thin layer of frost does not affect the cooling performance, but a thick layer will affect the unit's ability to maintain temperature efficiently and will eventually cause unit failure. If defrosting is necessary every month or more frequently, check the seals on the doors or call a technician for necessary maintenance.

1. Check the inside walls of the freezer weekly
    a. When frost has accumulated to a thickness of approximately one cm, the unit requires defrosting.
    b. The more the unit is opened and closed, frost will build quicker.
    c. Follow the manufacturer's specific recommendations for defrosting a freezer.
2. Remove all vaccine (from both compartments if using a combination refrigerator/freezer).
3. Place all vaccine in an alternate storage unit(s) that will maintain correct temperatures.
4. Turn off the power to the unit you are defrosting and unplug the unit.
5. Remove all frozen packs (keep frozen if possible).
6. Keep the freezer door open to allow the frost to melt.
7. Remove loose ice by hand to speed the process, but do not use sharp tools
8. Defrosting time can be reduced by placing a container of warm water (not boiling hot) inside the compartment.
9. Once the frost is melted completely, clean the freezer compartment thoroughly and wipe dry.
10. Clean refrigerator compartment as well
11. Connect the power, ensure that the thermostat is turned on and set correctly.
12. Wait for temperature to stabilize at the proper range before returning vaccine to defrosted unit. This may take hours or a day depending on the unit, so monitor with a calibrated temperature monitoring device.
13. Monitor and record the temperature frequently (every hour for several hours).
14. Re-stock the unit with vaccine once the temperature is stabilized.
15. Continue to monitor the temperature after the vaccine is returned to the unit.

For more information on vaccine storage and handling, refer to the CDC *Vaccine Storage and Handling Toolkit at* http://www.cdc.gov/vaccines/recs/storage/toolkit/

VFC TIP SHEET – PRODUCTS WITH MULTIPLE NDCS

An important issue regarding any vaccine product with multiple national drug codes (NDCs) for different pieces or components is that the only NDC that can be used to order, to report inventory, or to submit vaccine returns is the one listed on the CDC contract. Following is an example product with multiple NDCs.

GSK – Rotarix

1	Main Box	NDC: 58160-0805-11	Lot: A41CA734A	Expiration: 05/09/2010
2	Lyophilized Vaccine Box	NDC: 58160-0805-10	Lot: A41FA734A	Expiration: 05/09/2010
3	Diluent Syringes Pack	NDC: 58160-0805-02	Lot: A41DA734A	Expiration: 06/14/2011

The only NDC that can be used to order, to report inventory, or to submit vaccine returns is the one listed on the CDC contract. Using the example above, NDC 58160-0805-11 appears on the outside of the main box (1) of Rotarix and this is the number that is listed on the CDC contract. The lyophilized vaccine vials box (2) is NDC is 58160-0805-10 and the packet of diluent syringes (3) is NDC is 58160-0805-02. **The number used when placing vaccine orders, reporting inventory and submitting vaccine returns is NDC 58160-0805-11, which is listed on the outside of the main box (1).**

VFC TIP SHEET – VACCINE STORAGE UNIT CHECKLIST

Proper vaccine storage equipment is an insurance policy to protect patients' health, safeguards providers against costly vaccine replacement, inadvertent administration of compromised vaccine, and other potential consequences (e.g., the costs of revaccination and loss of patient confidence in your practice). Reliable, properly maintained equipment is critical to the vaccine cold chain. While the Illinois Department of Public Health (IDPH) or the Centers for Disease Control (CDC) and Prevention does not recommend specific brands of vaccine storage units, CDC does provide guidance on types of storage units that offer greater assurance of proper temperatures for vaccine storage based on equipment testing by the National Institute of Standards and Technology (NIST).

General Vaccine Storage Unit Recommendations

- ☐ Maintain required vaccine storage temperatures
  - Refrigerator: between 35F and 46F (2C and 8C)
  - Freezer: between -58F and +5F (-50C and -15C)
- ☐ Be frost-free or preferably have an automatic defrost cycle
  - If a manual defrost is used, the provider should be diligent in periodic defrosting according to manufacturer recommendations or if there is a two-inch or greater ice build-up in the freezer. Ice build-up in the freezer will diminish the equipment's capability to maintain correct storage temperatures. Even manual defrost combination refrigerator/freezers cycle and as mentioned above, cycling can affect storage unit temperatures.
- ☐ Have enough room to store the year's largest inventory without crowding
  - We recommend maintaining vaccine inventory to last five weeks, but no more than three months.
- ☐ Have enough room to store water bottles (in the refrigerator) and frozen coolant packs (in the freezer) to stabilize the temperatures and minimize temperature excursions that can impact vaccine potency
  - In the National Institute of Standards and Technology (NIST) 2009 study on stand-alone refrigerators, the typical volume of water bottles used in testing was equal to three percent to five percent of the total refrigerator capacity. In the NIST 2010 study on dual zone combination style refrigerators and pharmaceutical grade refrigerators, the volume of water bottles used was equal to four percent of the total refrigerator capacity.
- ☐ Have a certified calibrated thermometer placed in a central location inside each storage unit
- ☐ Reliably maintain the appropriate vaccine storage temperatures year-round
- ☐ Be dedicated to the storage of vaccines. Food and beverages should NOT be stored in a vaccine storage unit
- ☐ The vaccine storage unit door must fit securely and tightly against the unit. There should be no gaps between the seal and the body of the unit when the door is closed

Disclaimer: This tip sheet provides guidance on vaccine storage equipment to protect vaccines against equipment failure. Should temperature excursions or equipment failure occur, please refer to the Vaccine Incident Report for additional guidance.

For more information on vaccine storage equipment, please refer to the CDC *Vaccine Storage and Handling Toolkit* at http://www.cdc.gov/vaccines/recs/storage/toolkit/

GLOSSARY OF IMPORTANT VFC TERMS

Advisory Committee on Immunization Practices (ACIP)

The ACIP consists of 15 experts in fields associated with immunization who have been selected by the HHS Secretary to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and CDC on the control of vaccine-preventable diseases. The Committee develops written recommendations for the routine administration of vaccines to children and adults in the civilian population; recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications. The ACIP is the only entity in the federal government that makes such recommendations. VFC resolutions passed by the ACIP form the basis for VFC program policies on vaccine availability and usage. They may not necessarily match the general usage recommendations of the ACIP, but rather represent the rules that providers must follow for administering each specific vaccine under the VFC program.

Centers for Medicare and Medicaid Services (CMS)

Agency that provides oversight of the Medicare and Medicaid programs. Funding for VFC program is allocated through this agency.

CHIP (Children's Health Insurance Program)

Authorized under Title XXI of the Social Security Act, jointly financed by the Federal and State governments and administered by the States. The program provides insurance to children in families with incomes that are above Medicaid eligibility but do not have access to private insurance. Within broad Federal guidelines, each State determines the design of its program, eligibility groups, benefit packages, payment levels for coverage, and administrative and operating procedures.

In Illinois, All Kids is the State's CHIP. Children with CHIP are considered insured and are NOT considered VFC-eligible. CHIP (All Kids) recipients are eligible for vaccines purchased by the State (rather than by VFC) and distributed through the VFC program. The VFC eligibility for CHIP (All Kids) recipients should be documented as "V06 VFC Eligible-State specific eligibility (e.g. S-CHIP)." All other types of Medicaid coverage or if All Kids coverage is not able to be determined, eligibility should be documented as "V02 VFC Eligible-Medicaid/Medicaid Managed Care."

Deputization Agreement

A formal agreement through a Memorandum of Understanding (MOU), whereby Federally Qualified Health Centers (FQHCs) or Rural Health Clinics (RHCs) delegate their VFC authority for vaccinating underinsured children to local health departments (LHDs), who then vaccinate underinsured children as agents of the FQHC/RHC.166.

A current, approved MOU does not have an expiration date and does not need to be completed annually. The only time a new one MOU needs completed is when there is a change in Medical Director at the LHD. A change in administrator at IDPH, the FQHC/RHC, or LHD WILL NOT require the completion of a new MOU.

For more information on deputization agreements, please contact the VFC administrator at Linda.Kasebier@illinois.gov or 217-785-1455.

Department of Health and Human Services, Office of Inspector General (OIG)

Office mandated to protect the integrity of Department of Health and Human Services (HHS) programs and their beneficiaries. It is generally responsible for identifying, communicating and correcting activities of waste, fraud or abuse within HHS programs.

Family Planning Clinic

Clinic or provider whose main purpose is to prescribe contraceptives. This does not included school-based clinics or any VFC-enrolled provider whose main services are primary or acute care services.

Federally Qualified Health Center (FQHC)

Health center that is designated by the Bureau of Primary Health Care (BPHC) of the Health Services and Resources Administration (HRSA) to provide health care to a medically underserved population. FQHCs include community and migrant health centers, special health facilities such as those for the homeless and persons with acquired immunodeficiency syndrome (AIDS) that receive grants under the Public Health Service (PHS) Act, as well as "look-alikes," which meet the qualifications but do not actually receive grant funds. They also include health centers within public housing and Indian Health Service centers.

Federal Register

The Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents.

Federally Vaccine-eligible Child

Also known as VFC-eligible Child. A child who is eligible to receive VFC vaccine.

Fraud

An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Fully Insured

Anyone with insurance that covers the cost of vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.

Indian (American Indian or Alaska Native)

As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603):

"Indians" or "Indian", unless otherwise designated, means any person who is a member of an Indian tribe, as defined in subsection (d) of this section, except that, for the purpose of sections 1612 and 1613 of this title, such terms shall mean any individual who (1), irrespective of whether he or she lives on or near a reservation, is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in

the first or second degree, of any such member, or (2) is an Eskimo or Aleut or other Alaska Native, or (3) is considered by the Secretary of the Interior to be an Indian for any purpose, or (4) is determined to be an Indian under regulations promulgated by the Secretary.

(d) "Indian tribe" means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 et seq.], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

Insurance

For the purpose of the VFC program, "insurance" is defined as a plan that is:

- Regulated by a State's Insurance Commissioner and/or
- Subject to the Employee Retirement Income Security Act of 1974 (ERISA). ERISA is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for individuals in these plans.

Maximum Regional Charge

The amount that a VFC-enrolled provider can charge a non-Medicaid VFC-eligible child for each vaccine administered (also known as the administration fee or "admin fee"). State Medicaid agencies have the authority to reimburse at a lower level. The Centers for Medicare and Medicaid Services (CMS) has the responsibility of setting and adjusting the maximum regional charges. *See Federal Register.*

Medicaid

Federal and state partnership that creates a medical assistance plan for poor and disabled Americans. It is sometimes called Title XIX because it was authorized under Title XIX of the Social Security Act. VFC is part of the larger Medicaid program but has different eligibility criteria than the Medicaid assistance plan for both providers and participants.

Medicaid-eligible Child

A child who is eligible for the Medicaid Program. For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance coverage by a state Medicaid program.

Medicaid Fraud and Control Unit (MFCU)

Unit responsible for investigating and prosecuting (or referring for prosecution) violations of all applicable state laws pertaining to fraud in the administration of the Medicaid program, including the VFC program. In general MFCUs are located in the Office of the State Attorney General.

Office of Management & Budget (OMB)

Office that assists the President in overseeing the preparation of the federal budget and supervising its administration in Executive Branch agencies. OMB evaluates the effectiveness of agency programs, policies, and procedures.

Office of the State Attorney General (OAG)

Office that advises and represents state agencies that protect the rights of state consumers and may also represent other relevant state agencies. The Medicaid Fraud and Control Unit (MFCU) is located within this office in most states. *See Medicaid Fraud and Control Unit.*

Rural Health Clinic (RHC)

An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area. RHCs are required to be staffed by physician assistants, nurse practitioners, or certified nurse midwives at least half of the time that the clinic is open.

State Funds

State-contributed funds used to purchase vaccine for children who are not VFC-eligible or support program operations.

State Vaccine-eligible Child

Child who is eligible to receive vaccine that was purchased with state funds, usually off the federal CDC contract.

Underinsured Child

A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.

Uninsured Child

A child who has no health insurance coverage.

Vaccine Funding Source

How the three (VFC, 317, and state/local) funding sources to purchase vaccines.

- **VFC funds**: Federal entitlement funds used to purchase vaccines for administration to VFC-eligible children;
- **317 funds**: Federal funds that can be used to purchase vaccine for non-VFC eligible populations;
- **State funds**: State contributed funds used to purchase vaccines for individuals who are not VFC-eligible.

VFC Abuse

Provider practices that are inconsistent with sound fiscal, business, or medical practices, and that result in an unnecessary cost to the Medicaid program, and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient; or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

VFC-eligible Child

Also known as federally vaccine-eligible child

Child who is 18 years of age or younger and meets one or more of the following categories:

i. is an American Indian or Alaska Native; or
ii. is eligible/enrolled in Medicaid; or
iii. has no health insurance; or
iv. is underinsured and receives vaccine through a FQHC or RHC

VFC Funds

The Office of Management and Budget approves funding for the VFC program. Funding is through the Centers for Medicare and Medicaid Services to the CDC with awards made to 61 eligible awardees. Funding is used to purchase vaccines only for VFC-eligible children and support VFC-related activities, such as vaccine ordering and VFC and AFIX site visits.